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Supporting Private Public Dialogue

KVA: Creating the Veterinary Medicines Directorate

Impact assessment

Contents

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Impact assessment

KVA: Creating the Veterinary Medicines Directorate

1. Background

The Kenya Veterinary Association (KVA) is a professional membership organisation of veterinarians whose mandate is to promote the economic development and welfare of its members as well as to safeguard the health and welfare of animals. The Association acts as a resource centre for the veterinary profession, providing leadership and advocating proper management and high level of professionalism in the delivery of veterinary services.

Since 2008, BAF has supported KVA investing circa KES 13 million to advocate the separation of the regulation of veterinary medicines and the regulation of human medicines.

2. Outline of the projects

In 2008, BAF approved KES 3.5 million to facilitate research on veterinary medicines distribution. At the time, the regulation of both veterinary and human medicines was undertaken by the Pharmacy and Poisons Board (PPB). The PPB only had one veterinary surgeon on its Board out of a total 12 members. As a result, KVA argued that the capacity (as well as the motivation) of the PPB to enforce the regulation of veterinary medicines was limited. The consequence was that, due to poor enforcement, the uncontrolled sale of animal medicines as well as the sale of counterfeit medicines by distributors had grown significantly. This resulted in the availability of animal medicines not prescribed by the veterinary profession (but by either para-vets or simply over-the-counter) being widely available in the market.

Research showed that there was substantial misuse of veterinary medicines including the prevalence of counterfeit and substandard drugs which had led to rising public health concerns and greatly hindered access to markets for livestock and livestock products which were rendered non-compliant with international standards. This encouraged KVA to propose reforms to the regulation of veterinary medicines (including importation, manufacturing, registration, distribution, storage and usage) as regulated by the Pharmacy and Poisons Act (Cap 244).

In 2008, the National Livestock Policy was adopted and proposed separate regulation of veterinary medicines. In 2010, KVA received further BAF support of KES 3 million to make proposals to revise the draft Veterinary Medicines (VM) Bill, 1998, in partnership with the Ministry of Livestock Development (MoLD) and other veterinary stakeholders. By the end of the year, KVA had engaged with stakeholders to review the VM Bill and also widely publicised their position in the

press. However, their advocacy took a back seat as a result of the development of constitutional Bills after the promulgation of the Constitution of Kenya, 2010.

The VM Bill was published in 2010 but faced resistance from pharmacists who wanted the status quo to prevail. This affected the progress of the Bill through Parliament and it expired with the term of Parliament in 2012.

Whilst this project was underway, KVA also engaged government on a separate draft Bill on the regulation of veterinary professionals. KVA sought agreement from BAF to utilise some of the approved funds to participate in the discussion. KVA made various proposals to parliament on this Bill including the expansion of the Bill to cater for both veterinary surgeons and veterinary paraprofessionals. This led to the Veterinary Surgeons and Veterinary Paraprofessionals (VSVP) Act No. 29 of 2011. The Act provided for the establishment of the Kenya Veterinary Board (KVB) which was tasked to implement the Act. Importantly, section 39 stated that the Cabinet Secretary would establish additional institutions to manage the animal resource industry effectively. These included a Veterinary Medicines Directorate (VMD), an animal health inspectorate service, the Kenya Livestock Research Institute and the Kenya Marketing and Development Authority. In essence, this section put in motion the separation of the regulation of veterinary medicines from human medicines. The VMD was expected to ensure appropriate manufacture, importation, distribution and safe use of veterinary medicines.

In 2012, BAF approved a grant of KES 4.9 million to KVA to support the reintroduction of the VMD Bill and the development of VMD Regulations. However, the Attorney General later advised the Ministry of Agriculture Livestock and Fisheries (MoALF) to shelve the VMD Bill as the proposal for a veterinary medicines directorate was already covered in the VSVP Act.

KVA then partnered with the State Department of Livestock in the MoALF to develop draft VMD regulations. The objective of the regulations was to provide the legal framework that assures professional control in the distribution and use of veterinary medicines and to reduce their misuse and abuse in the country. The VMD regulations were drafted and subjected to five regional workshops and a national stakeholder workshop. The proposed regulations provided for the regulation of the manufacture, importation, exportation, registration, distribution, prescription and dispensing of veterinary medicines and poisons as provided in section 39(2)(a) of the VSVP Act. KVA completed its policy position on the regulations which they agreed with the Kenya Veterinary Board (KVB) and then submitted to the MoALF.

In January 2013, the Statutory Instruments (SI) Act, Number 23 of 2013 was enacted. This provided a new procedure to gazette subsidiary laws requiring that they be subjected to a Regulatory Impact Assessment (RIA) and approved by the appropriate Parliamentary Committee before gazetting. To finalise the process of developing appropriate VMD regulations, KVA received a top-up grant of KES 1.6 million to obtain stakeholder input into the proposed regulations; to provide the resources for the MoALF complete the RIA; and to lobby the Parliamentary Committee for Agriculture to approve the regulations before gazetting.

3. Outcome

As a result, KVA:

- In partnership with the Directorate of Veterinary Medicine, the Attorney General Chambers, State Department of Livestock (SDL) and the Kenya Veterinary Board (KVB) finalised the regulations ensuring all stakeholder input was considered.
- Engaged various stakeholders including the Pharmaceutical Society of Kenya (PSK) and the veterinary pharmaceutical industry players including those in manufacturing, wholesaling distributing and retailing veterinary medicines.
- Supported the KVB in completing the RIA. The assessment was carried out as guided to the procedures set in the SI Act to estimate the impact of the Veterinary Medicines Directorate Regulations to animal and human health and welfare as well as the impacts on the veterinary medicines industry players. The main purpose was to formulate rational regulations which assure greater benefit to the industry and society as compared to the costs of compliance. (The cost-benefit analysis looked at three options – implementation of the VMD regulations, self-regulation and no change and concluded that implementation gave the greatest benefit)[1].
- Supported the MoALF to meet the constitutional requirement for public participation.
- Drafted an explanatory memorandum on the regulations and engaged in dialogue with the SDL and Cabinet Secretaries and Permanent Secretaries of both the Ministry of Health and the MoALF. They engaged, and successfully lobbied, the Attorney General Chambers, the Pastoral Parliamentary Group and the Parliamentary Agricultural Committee on Delegated Legislation for the adoption of the VMD regulations.
- Organised workshops to build the capacity of the MoALF for the official launch of the VMD.

The Ministry of Agriculture gazetted the Veterinary Surgeons and Veterinary Professionals (Veterinary Medicines Directorate) Regulations, 2015, Kenya Gazette supplement no. 174 after their adoption by parliament in October 2015.

VMD's management was established and vested in a Council appointed as outlined in the VMD regulations. The VMD council members were gazetted in October 2016 through the Kenya Gazette No. 9123. The members of the Council hold office for a term of three years and are eligible for re-appointment for one further term. KVA initially nominated a list of their members, with the required specific technical requirements, to the Kenya Veterinary Board. The KVB selected three veterinary surgeons and one veterinary technologist as mandated by the regulations to be appointed to the Council.

After the gazetting of the regulations, in November 2016, the Kenya Pharmaceutical Distributors' Association (KPDA) took the Kenya Veterinary Board and the Veterinary Medicines Directorate to court seeking to halt the

[1] Report of Regulatory Impact Assessment. Prepared and concluded by Kenya Veterinary Board, 12 January 2015

implementation of the VMD regulations (Petition number 457 of 2016[2]). The Pharmacy and Poisons Board and Kenya Veterinary Association were enjoined in these proceedings as interested parties. The petition was declined by the High Court in September 2017.

This delayed implementation, however, which thus only began in October 2017. The VMD was officially launched in November 2017 at a conference organised by the Global Alliance for Livestock Veterinary Medicines (GALVmed)[3].

KVA is represented in the transitional committee that works out the implementation methodology from the old regulatory system of managing veterinary medicines to a new system. This is not the formal committee outlined in the VMD regulations. However, the VMD has requested KVA to participate in this process.

KVA is also represented on the committee which is developing draft amendments to the VSVP Act that have been proposed by the Kenya Veterinary Board.

4. Impact

4.1 Qualitative assessment

The key outcome of the VMD regulations is the separation of the regulation of veterinary medicines from human medicines. These regulations set up the VMD which is a new agency with the vision to be a world-class regulatory body promoting the responsible, safe and effective use of Veterinary Medicines and other animal health products.

For one to trade in or dispense veterinary medicines at any level, one must be licensed by the VMD. Ultimately all veterinary medicine supply chain actors (i.e. suppliers, wholesalers, retailers, exporters, importers and some veterinary professionals) will have to be registered by the VMD which would, if well implemented, reduce the prevalence of both unauthorized personnel working at the Agro Vets and the prevalence of counterfeit medicines being dispensed at the Agro Vets.

The VMD categorises veterinary medicines and the qualification of persons authorised to trade in each category and reviews the categories every five years. The Council may grant the renewal of registration and retain records of the movement of all veterinary medicines for a period not exceeding five years. KVA stated that the efficiency of the process of registering products had increased in that while before it was taking over three years at the Pharmacy and Poisons Board, it is now taking about half the time. This is because the VMD is now focused solely on veterinary medicines. KVA played a role in advocating this efficiency functionality. Through the transitional committee meetings, KVA guides the formulation of VMD's administrative processes to have smooth operational procedures at the VMD.

[2] Kenya Law Cases: http://kenyalaw.org/caselaw/cases/view/144015/. Accessed on 16 July 2018.
[3] GALVmed Press statement: https://www.galvmed.org/news/agency-regulate-veterinary-medicines-kenya-launched/ Posted on 24 November 2017.

The VMD regulations require a technical expert to be present at each Veterinary Medicine Outlet to advise farmers. This has led to an increase in employment opportunities for technical experts at the Agro Vet locations. Failure to employ qualified practitioners could result in the closure of an Agro Vet store by the VMD inspectors. Previously Agro Vets facilities were being operated by farmers or agriculturists who may have unknowingly misguided the public.

Additionally, KVA stated that their members have reported that some pharmacy outlets have stopped stocking veterinary medicines. This is a direct result of the VMD regulations which make it illegal for pharmacists to dispense veterinary medicines unless they have a Veterinary Surgeon present at their outlet. As a consequence, this is slowly correcting malpractices by agriculturalists, livestock technicians, pharmacists and other groups by avoiding the misuse of veterinary drugs from unlicensed practitioners. Also, it is making it harder for unlicensed distributors to access veterinary medicines. KVA does not have data to support these claims but has been gathering members' anecdotal responses.

The VMD now utilises the Kenya Trade Network Agency (KENTRADE) portal that facilitates cross-border trade, to authorise and approve import permits of veterinary medicine. This has reduced the wait time for clearance of all importers' products at the port. KVA has received positive feedback from their members who can now register their businesses with the surety that the clearance timeline would not be a risk factor to their business failing. Although KVA does not have evidence for this, they asserted that there is an improved business environment as the majority of KVA members, veterinarians and para-veterinarians, have opened more Agro Vet outlets.

This regulation, albeit good for the sector, has led to double regulation of the manufacture of drugs in the country. The Kenya Pharmaceutical Distributors' Association (KPDA) have explained that human and veterinary drugs are often manufactured by the same companies[4]. The PPB has over the years conducted Good Manufacturing Practice (GMP) inspections for manufacturers in the country annually at a cost of USD 1,000. With the VMD regulations, these manufacturers are now subjected to two inspections, one from PPB and one from VMD. According to PSK, there are 34 drug manufacturers in the country with 12 (35%) producing both human and veterinary medicines[5]. They are subjected to GMP inspection fees from both the PPB (annually) and the VMD (every 3 years) so the VMD regulations have increased the cost of compliance for GMP inspection of veterinary medicine manufacturers by US$333 or around 33 per cent and is a minimal additional cost to ensure that veterinary medicines meet the required standards.

PSK argues that the PPB has the expertise and experience to conduct GMP inspections effectively and efficiently but that VMD lacks the expertise and so will be less effective. KVA counters that this is a transitional issue being discussed between VMD and PPB. VMD has developed GMP dossiers and the PPB staff

[4] Distributors warn of price hikes over double regulation. Jamah A. 2016. The Standard Newspaper. www.standardmedia.co.ke/health/article/2000219819/distributors-of-veterinary-medicines-warn-of-price-hikes

[5] The companies manufacturing both human and veterinary medicines are Norbrook Kenya Ltd.; Cosmos Ltd; Universal Corporations; Laboratory & Allied Ltd.; Biodeal Laboratories Ltd.; Sphinx Pharmaceuticals; Hightech Pharmaceuticals; Aesthetics Limited; Ultravetis E. A. Ltd.; Dawa Ltd.; Unga Farmcare; and Bimeda Ltd.

members formerly dealing with veterinary medicines have moved to VMD. KVA is engaging with veterinary medicine manufacturers, PPB, VMD and other stakeholders to inform them and ensure they adopt the new requirements under the regulatory change.

KVA stated that public awareness of the regulations is still underway. However, the exporters and importers have had to comply, and are therefore more aware of the new regulations. VMD will, together with KVA, organise various fora to enlighten stakeholders about the regulations. The VMD is setting up the systems of pharmaco-vigilance which will track the distribution and use of veterinary medicines across the supply chain. This will safeguard the trade and use of veterinary medicines thus improving animal and human health.

It would have been illuminating to say how many agro vets had now been licensed by VMD, how many drugs had been approved and the value of veterinary medicines drugs that have been imported and exported but VMD was unable to share this information.

In a parallel activity, KVA in partnership with KVB and with support from Kenya Commercial Bank Foundation Initiative, is creating a livestock identification and traceability database to track all animal products from "the farm to the fork". KVA hopes that when the VMD is fully functional, they will join hands with KVB in this initiative. It is expected that this will lead to safer animal products for domestic and international consumption with more products passing the health and drug level tests. This will support the creation of more livestock disease free zones in Kenya and open up new export markets for Kenyan animal products. It will also improve market access for meat, milk and other animal products as envisioned in Vision 2030.

Market access for meat is dependent on animals meeting sanitary standards set by the destination market, and the World Organisation for Animal Health (OIE) standards (i.e. terrestrial code). OIE standards are recognised by the World Trade Organisation as the reference international sanitary rules[6]. Kenya is a signatory to the OIE standards and KVA has been working with the State Department of Livestock to implement the recommendations of the periodic OIE gap analysis conducted every five years.

The management and control of veterinary medicines is a key component towards meeting the OIE sanitary standards. Sanitary standards for animals are largely defined by meeting defined maximum residue levels and the absence of diseases. Other factors required to export include[7].

- Traceability of animals from birth to export including the documentation of the treatment of these animals for diseases, and the medicines used.
- Functional disease free zones where animals are compartmentalised and treated over a 6 month before their slaughter and sale. An additional requirement is lab tests to verify that animals are disease free.

[6] www.oie.int Website accessed on 13 Sep, 2018
[7] Vet on call: What it'll take you to export live animals. Mugahia A. Dr. Seeds of Gold supplement, Daily Nation. 18 Nov 2018: https://www.nation.co.ke/business/seedsofgold/All-it-takes-to-export-livestock/2301238-4191090-14jbiv9z/index.html. Website accessed on 13 Sep, 2018

- The regulation of professionals to ensure that animals receive quality care[8], and animal welfare.

Improved regulation of veterinary medicines should contribute to Kenyan meat producers being able to access export markets for Kenyan livestock products.

There is a draft Health Laws Amendment Bill, 2018[9] that has been approved by the Health Committee of the National Assembly. The Bill essentially seeks to return the functions of the VMD back to the PPB. The PPB Board will be formed by a chief pharmacist, Director of Medical Services, and the Director of Veterinary Services among others. The Chairman of both the VMD and the KVA have been attending Parliamentary Committee meetings on the delegated legislation to discuss the draft Bill with the aim of having the veterinary medicine aspects withdrawn from that Bill.

If the VMD regulations are implemented well, it is expected that there would be better management and quality controls in the supply chain of veterinary medicines. However, due to the delays in the operationalisation of the VMD, it is not possible to estimate the economic impact of these regulations on the Kenyan economy.

5. Outstanding issues

During the current transition period, implementation of the VMD regulations has had some challenges as outlined below:

- Some pharmacists are still selling veterinary medicines which demonstrates the need for more VMD staff on the ground to enforce the regulations.
- There have been some public awareness challenges with the Kenya Ports' Authority at the Customs and Declaration department looking for the PPB approval letters as opposed to the new VMD approvals. KVA addressed this issue by having a letter to be sent from the MoALF stating that all releases and approvals for any matters relating to veterinary medicines need to be made by the VMD.
- The release of prior dossiers regarding all veterinary medicine records held by the PPB as well as the monies remitted to PPB by various market actors after the successful gazetting of the VMD. KVA is already supporting the VMD to dialogue with PPB to smoothen the implementation process.
- KVA members have stated that the VMD fees have led to increased costs to operate their businesses. KVA is planning to address these concerns at the VMD sensitisation and implementation workshop which will allow their members, as well as other regulated parties, understand the roles of VMD and KVB, and if need be further investigate their fee claims.

[8] www.oie.int

[9] Kenya gazette supplement no. 36, special issue (10 April 2018). www.kenyalaw.org

6. Lessons learned

KVA stated that the following were the key lessons from their advocacy:

- Removing regulatory powers from an existing regulatory Board such as the change to PPB is a difficult process. This has been illustrated by both the KPDA case and the proposed Health Amendment Bill.
- There can be unforeseen consequences, as for example with the additional GMP inspection fees, and considerable effort is required to ensure that all possible consequences are considered and addressed before new regulations are adopted.