

Review of the policy, regulatory and administrative framework for delivery of livestock health products and services in Eastern and Southern Africa

Prepared for GALVmed by

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Abbreviations and acronyms

AFRISA	Africa Institute for Strategic Animal Resource Services and Development
ASAL	Arid and semi-arid lands
CAHWs	Community-based animal health workers
CBPP	Contagious bovine pleuropneumonia
CGMP	Current good manufacturing practices
CPD	Continuing professional development
CTTBD	Centre for Ticks and Tick-borne Diseases
DFZs	Disease-free zones
DVOs	District Veterinary Officers
DVS	Director of Veterinary Services
ECF	East Coast fever
FAO	Food and Agriculture Organization of United Nations
FMD	Foot and Mouth disease
GALVmed	Global Alliance for Livestock Veterinary Medicines
GDP	Gross domestic product
KALT	Kenya Association of Livestock Technicians
KEVEVAPI	Kenyan Veterinary Vaccines Production Institute
KLIFT	Kenya Livestock Finance Trust
KVA	Kenya Veterinary Association
KVAPS	Kenya Veterinary Association Privatization Scheme
KVB	Kenya Veterinary Board
MVA	Malawi Veterinary Association
NAADs	National Agriculture Advisory Services
NDA	National Drug Authority
NGO	Non-governmental organisation
NVI	National Vaccine Institute
OIE	Organization Internationale des Epizooties
PPB	Pharmacy and Poisons Board
SADC	Southern African Development Community
SHG	Self-help groups
TADs	Trans-boundary animal diseases
TAVEPA	Tanzania Veterinary Para-professional Association
TBS	Tanzania Bureau of Standards
TFDA	Tanzania Food and Drug Authority
ToRs	Terms of reference
TVA	Tanzania Veterinary Association
TVI	Tanzania Veterinary Institute
TVLA	Tanzania Veterinary Laboratory Agency
VAAM	Veterinary Assistants Association of Malawi
VCT	Veterinary Council of Tanzania
VSF	Vétérinaires Sans Frontières
VSVPP	Veterinary surgeons and veterinary para-professionals



Executive Summary

An analysis of national policies, strategies and legal framework (Acts of Parliament, subsidiary legislation and Ministerial decrees) related to the delivery of livestock health products and services in Uganda, Kenya, Tanzania, Malawi and Ethiopia was carried out. The review focused on how products (veterinary medicines, vaccines and field diagnostics) are registered and distributed to reach the farmers who rely on livestock for their livelihood. It also reviewed the actors involved in service delivery and the challenges or constraints that are encountered. Secondary data sources were reviewed. These included national, regional and international reports available as hard-copy published literature and as documents available over the Internet. Appropriate target respondents from government veterinary services, the veterinary boards and veterinary associations, schools of veterinary medicine, organizations involved in veterinary service delivery, Non-governmental organizations, community-based organizations and distributors of veterinary pharmaceuticals were identified in consultation with GALVmed, and their consent to participate in the study obtained. A list of the respondents who participated in this study is summarized in Annex 1. Though a questionnaire was developed for this study, it was later found to be more prudent to use a more general framework for data collection during interviews with the key respondents.

The veterinary services in the study countries have been affected both by external structural policies imposed by multilateral institutions and by internal policies imposed by national constitutions that have placed a major focus on the privatization of clinical services, devolution and citizen participation in decision making. According to the OIE, the quality of veterinary services of a country depends on a set of factors, which include fundamental principles of an ethical, organizational, legislative, regulatory and technical nature. Compliance with these fundamental principles by the veterinary services of a country is important in the establishment and maintenance of confidence in its international veterinary certificates required by veterinary services of countries that import livestock and livestock products. The OIE recommends a strong chain of command as a key pillar of effective veterinary services.

Before the onset of the structural reforms of the 1980s, central Government provided most of the veterinary services. With the reforms, central Government has tended to concentrate on regulatory, policy formulation and law enforcement functions. Central Government devolved animal health services to local government and to the private sector. Veterinary services in Uganda, Tanzania and Ethiopia have strong and almost independent local or regional authorities responsible

for service delivery, including animal health services in the field. Being relatively new entities, the local authorities lack adequate capacity for effective delivery of veterinary services and their linkage with the Central Veterinary Authority is weak. Kenya has strong centralized veterinary services, with a range of animal health services (clinical services, artificial insemination, etc.) devolved to the private sector. The country is in the process of devolving veterinary services to the County governments under the new constitution. Malawi has a centralized veterinary service, but the country has only eight veterinarians, making animal health service delivery an insurmountable task. The veterinary laboratories in all the countries are weak and most of the treatments are given based on clinical diagnosis, with no, or minimal, laboratory diagnosis. Tanzania has commercialized its veterinary laboratory services through the creation of the Tanzania Veterinary Laboratory Agency, which charges for all diagnostic services that it gives to livestock owners and to the Department of Veterinary Services.

The continuum of livestock health management has many actors, including the animal owners or farmers, animal health technicians (veterinary) and veterinarians who operate either individually or within private or public institutions. The roles of the actors are defined in legal frameworks. The legal frameworks range from Acts of Parliament as found in Kenya, Uganda, Tanzania and Malawi to Ministerial decrees or proclamations being used in Ethiopia. With the exception of Tanzania, which has a relatively new law on animal diseases (The Animal Diseases Act of 2003), the legal frameworks for disease control in the other countries are very old and need major revision and consolidation.

The legislations for the delivery of veterinary services (Veterinary Surgeons Act) in Tanzania and Kenya are relatively up to date and have established regulatory boards that define the specific roles of veterinary boards, veterinary surgeons, veterinary para-professionals, animal owners and private veterinary practice. The Veterinary Surgeons Acts in Uganda and Malawi are old and fail to incorporate veterinary para-professionals (animal health technicians with one to two years' diploma training in institutions recognized by veterinary boards) in the delivery of veterinary services. Ethiopia is at the initial stages of setting a proclamation to establish a veterinary board to regulate the training and registration of veterinarians and the delivery of veterinary services. The Kenya Veterinary Board and the Veterinary Council of Tanzania are examples of well-managed boards with good corporate governance for registering and licensing animal health service providers (qualified individuals and institutions).



The Animal Disease Act mandates the Director of Veterinary Services to provide policy guidelines in disease control, proscribe a list of notifiable diseases that require mandatory reporting when they occur and issue permits for the importation of veterinary biologicals. The animal owners have a pivotal role in livestock health management, as they are, by law, required to report the occurrence of a suspected notifiable disease to a veterinarian or any other official appointed by the Minister responsible for livestock. Extension services provided by relevant government departments (Livestock Production and Veterinary Services and NGOs) play an important role in raising the awareness of livestock owners on disease recognition, prevention and control. The veterinarians and animal health technicians are, by law, (Animal Diseases Act and Veterinary Surgeons Act or its equivalent) mandated to make disease diagnosis (clinical and laboratory), prescribe and administer treatments and vaccinations for disease prevention and control. Animal owners can buy vaccines from licensed suppliers to vaccinate their livestock; this is most common in the poultry sector. In all the study countries, veterinary laboratory services are weak and confirmation of disease-causing agents is rarely done. Treatments are carried out based on clinical diagnosis by the animal owner, veterinary para-professional (includes animal health technicians) and veterinarians. Point-ofservice diagnostic kits (field diagnostic kits) are not in use, but have potential in the huge pastoral areas.

The Veterinary Surgeons Act establishes veterinary statutory bodies (boards) that regulate the delivery of animal health services. The Act defines the qualification for registration as a veterinarian or veterinary paraprofessional, issues licenses to private veterinarians and para-professionals, registers and licenses institutions such as NGOs involved in animal health service delivery, and maintains a register of all registered veterinarians and veterinary para-professionals. In Kenya, it is an offence for persons who are not registered by the Board to charge for diagnosis, treatments or vaccination. NGOs offering animal health services must employ a registered veterinarian to be in charge of animal health and welfare. By law, only registered persons are permitted to provide livestock health services. The Act defines the services veterinary para-professionals can offer on their own or under the supervision of a registered veterinarian, and permits animal owners as well as unqualified persons to treat their own animals, or offer emergency treatment and undertake minor treatments. It is only in Uganda that CAHWs have been legally permitted to offer treatments and vaccinations in remote rural areas, under the supervision of government veterinarians. Discussions with key respondents in all the countries indicated that CAHWs provide animal health services in areas where veterinarians and veterinary para-professionals are not readily available, and livestock owners can purchase almost any veterinary pharmaceutical from pharmacies and agro-vet shops without prescription from veterinary surgeons.

The Pharmacy Boards (or their equivalent) regulate the registration, distribution and use of veterinary pharmaceuticals, including vaccines and diagnostic kits. It is an offence to import, manufacture for sale or offer for sale livestock health products that are not registered by the Board. Only the license/patent holder, the manufacturer or the local technical representatives of the license/patent holder or manufacturer can apply for registration of a drug, vaccine or diagnostic kit. Only registered pharmacists are licensed to sell veterinary pharmaceuticals in registered and licensed premises. Corporate bodies or partnerships selling veterinary drugs must have a registered pharmacist as a shareholder or as a partner, who is responsible for controlling the sale of drugs and must also apply for annual permits and licenses from the Board, as well as business permits from urban authorities. The role of the veterinarian is to provide prescriptions for prescription-only drugs (Part I poison; include antibiotics and vaccines), administer treatments and supervise veterinary para-professionals when they offer treatments. In all the countries, veterinarians and veterinary para-professionals are only legally permitted to sell non-prescription products such as those used in tick control. The Veterinary Boards and Pharmacy Boards have inadequate capacity to effectively regulate the delivery of livestock health products and services, and unregistered products are being sold by unlicensed persons. Ethiopia does not have a Veterinary Board and the boards in Uganda and Malawi have serious financial and human resource capacity, rendering them almost non-functional.

Except for a few major trans-boundary animal diseases, animal owners can access and purchase nearly all veterinary vaccines to vaccinate their animals based on their risk assessment. In some countries, such as Ethiopia and Kenya, the Government provides highly subsidized vaccines for the control of major trans-boundary animal diseases for the public good.

The regulation of veterinary pharmaceuticals in Kenya, Malawi, Tanzania and Uganda is under the control of institutions (Pharmacy Boards) under the Ministry of Health. Ethiopia has devolved this function to an institution within the Ministry of Livestock, the Veterinary Drug and Animal Feed Administration and Control Authority. In countries where the regulation of veterinary pharmaceuticals is by institutions within the Ministries of Health, the veterinary profession is grossly underrepresented and registration of livestock health products is rarely a priority. In addition, the distribution of livestock health products is tightly controlled by pharmacists, and it is illegal for veterinary surgeons to distribute veterinary pharmaceuticals in the absence of a registered pharmacist. In Kenya, Uganda and Tanzania, there is very strong indication that the veterinary Boards would want to legally have full control of the regulation of veterinary pharmaceuticals.



1 **Objectives**

This study was commissioned by GALVmed in order to understand the policy constraints of and opportunities for using actors outside the public sector/government mechanism in the delivery of livestock health products and services. The results of this study will inform GALVmed's market development, adoption and global access strategies.



2 Methodology

The policy landscape study obtained the required information through an extensive desktop review of relevant literature and interviews with key informants from public and private institutions involved in the delivery of veterinary services in the selected countries (Annex 1). The primary sources included the national policies, strategies, Acts of Parliament and subsidiary legislation, including Ministerial Decrees, related to the delivery of livestock health products and services. Secondary sources included a literature review of national, regional and international reports and relevant studies. The authors also took into account international initiatives, debates and trends, particularly those under the auspices of, e.g., the OIE, AU-IBAR and other relevant organizations.

The respondents included representatives drawn from the government veterinary service (e.g. Director of Veterinary Services, veterinary officers, veterinary para-professionals and Veterinary boards) and private

sector animal health service providers, including veterinary associations. Other respondents were public and private sector veterinarians, veterinary para-professionals, community animal health workers (CAHWs), non-governmental organizations (NGOs), distributors and retailers of livestock health products and manufacturers of vaccines, as well as livestock farmers and farmers' organizations, where possible.

Livestock owners are key actors and the primary beneficiaries of effective delivery of livestock health products and services. Due to time limitations, no meaningful interviews were conducted with the livestock owners. This remains a key weakness of the study. In addition, only actors within the urban centers were accessible. In Ethiopia, access to key documents was not possible and, even where possible, the documents were in Amharic.



3 Review of country veterinary administrative structures and legislative framework

In the last three decades, the veterinary services in Kenya, Uganda, Tanzania, Malawi and Ethiopia have progressively moved from a centralized administrative structure with a strong chain of command to a combination of a centralized system with varying degrees of decentralization. These changes have been driven both by external forces, such as the Structural Adjustment Programmes , and internal forces, such as national constitutions and regulatory framework. A brief review of the veterinary administrative structures in these countries is summarized below.

3.1 **Kenya**

The Department of Veterinary Services in Kenya is currently within the Ministry of Agriculture, Livestock, and Fisheries. The Ministry is headed by a Cabinet Secretary, and the Director of Veterinary Services (DVS), or Chief Veterinary Officer (CVO), is the head of Veterinary Services. The veterinary services discharges its disease control mandate through an administrative structure with a clear chain of command, from the DVS through a hierarchy of regional and district veterinary officers, divisional veterinary officers and animal health technicians, and collaborates with private sector providers of animal health services. Kenya has over 2,000 veterinarians and over 4,000 veterinary para-professionals. Devolution of veterinary services in line with the new Constitution has the potential for conflicts if county governments refuse to comply with disease control policies, such as the closure of livestock markets to control a disease outbreak, as this would interfere with their revenue streams.

3.2 **Uganda**

The Department of Livestock Health and Entomology under the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF) has the mandate to investigate and control animal diseases, protect humans against communicable diseases from animals to humans,

control vectors such as tsetse and ticks, amongst others, and certify and enforce compliance of veterinary regulations. A Commissioner of Livestock and Entomology heads the veterinary services. The veterinary services are under the central Government and the local government. The central Government is entrusted with responsibility in all areas of animal health, including national animal disease prevention and eradication programmes. It formulates and reviews policies on the control of animal diseases, including zoonoses; examines laboratory samples from the districts; acts as a technical support for animal disease surveillance and control; and advises the district authorities and decision makers on effective and efficient animal disease control strategies. In the late 1980s and early 1990s, Uganda decentralized and privatized clinical veterinary services to local government and the private sector, and downscaled the civil service. Clinical services, breeding and tick control were privatized, whilst the vaccination of animals against epidemic diseases, quarantines and tsetse control were retained by MAAIF. In each district, the local authority determines three priority agricultural enterprises to be funded; thus livestock could be a priority in one district and not in the neighbouring district. This makes disease control very challenging and can affect the national economy through losses in export or food insecurity.

3.3 Tanzania

Veterinary services in Tanzania are within the Ministry of Livestock and Fisheries Development and have a central component under the Director of Veterinary Services and a regional component under the local authorities. The Director for Veterinary Services (DVS) is mandated to maintain a list of all the notifiable diseases; to issue the official position on the method to be used in the diagnosis, control, treatment, disposal and quarantine for each notifiable disease; to establish and maintain a national veterinary laboratory system; and to regulate the use of animal pesticides, vaccines and other related products.



The Minister responsible for livestock can issue regulations spelling out measures for checking and handling livestock disease outbreaks, including the technical steps to be taken in order to effect quarantine and define epidemiological demarcations for buffer zones and infected areas, and the applicable movement restrictions for each zone or area. Veterinary laboratories are under the Tanzania Veterinary Laboratory Agency, created under executive authority, and it provides commercial diagnostic services to the veterinary department and animal owners. Tanzania is divided into 26 regions under local government. The district councils under the local government are responsible for the delivery of veterinary services in the field. The linkage between the local government technical staff and the central veterinary services is weak, and the DVS does not have overall control of animal health services implemented in the field.

3.4 Malawi

Veterinary Services in Malawi is under the Ministry of Agriculture and is centralized, with no devolved functions. The Department of Animal Health comprises three divisions: Research and Development; Animal Production and Extension; and Animal Health and Disease Control. There are only eight veterinarians in Malawi, with two in central government administration, three in the veterinary laboratories and three in the field as private veterinarians. Veterinary field services are greatly constrained by the low number of veterinarians; there are no veterinarians in any of the 29 districts. Veterinary laboratory diagnostic services are provided by the central veterinary laboratory in Lilongwe. The Center for Ticks and Tick-borne Diseases (CTTBD) that manufactures vaccines has been identified as an African Union technical services center (AU-CTTBD) and presents a good model for the commercialization of vaccines that are developed by International Research Institutes. The AU-CTTBD sells the ECF vaccine to the private sector for distribution to the farmers.

3.5 Ethiopia

Since 1992, Ethiopia has developed a federal system based on ethnically-defined regional states. Each region has its own Bureau of Agriculture with responsibility for veterinary services (the Government authorizes the purchase of veterinary pharmaceuticals through the regional bureaux). At the Federal level, the Department of Veterinary Services within the Ministry of Agriculture has an important coordinating role in disease control and veterinary policy.

The veterinary service in Ethiopia is within the Ministry of Livestock and is headed by a Director of Veterinary Services. The central Government has the overall mandate on disease control and eradication and sets the relevant policies. Federal and regional governments are responsible for the quality and standards of animal health service. Animal health service provision is dominated by the public sector and over 90% of veterinarians work in the public sector; there are over 5,000 animal health staff in the public sector. The Federal animal health service has retained policymaking and regulatory functions and service delivery has been devolved to the regional governments; there are eight semi-autonomous regions in the country. Regional animal health services are provided through clinics and animal health posts; the clinics are staffed by veterinarians, animal health assistants and animal health technicians. Participation of the private sector in the delivery of veterinary services is low and most of the participants operate drug shops and import veterinary pharmaceuticals. Clinical and diagnostic services are minimal and operate around Addis Ababa, where there are commercial livestock farms. Most of the vaccines used in the country are manufactured by the National Vaccine Institute.





4 Analysis of key findings



The study reviewed the policies on the delivery of veterinary services and the development of the livestock industry in Kenya, Uganda, Tanzania, Malawi and Ethiopia and the roles played by the public and private sectors in delivery of livestock health products and services. The policy framework in all the countries is summarized in Annex 5. The study also analyzed the consistency between policy and practice. Key stakeholders in the delivery of livestock health products and services were interviewed using questionnaires (Annexes 2, 3, 4 and 6). The analysis addressed key issues in the terms of reference (Annex 1) of this study and also identified the extent to which policies were adhered to in respect of the registration, distribution, sale and use of livestock health products and service delivery. The policy review and analysis of the findings for each country is presented below.

4.1 **Kenya**

The delivery of livestock health products and services is regulated by the Animal Diseases Act (CAP 364), the Veterinary Surgeons and Veterinary Para-professionals Act (No. 29 of 2011), herein referred as VSVPP Act, the Pesticide Products Act (CAP 346) and the Pharmacy and Poisons Act (CAP 244) (Annex 5).

The key actors with legal recognition for the delivery of livestock health products and services include the livestock owners, registered veterinary surgeons and veterinary para-professionals (animal health technicians), the Director of Veterinary Services (DVS), licensed manufacturers, registered distributors and retailers, institutions training animal health service providers, licensed non-governmental organizations (NGOs) and farmers' organizations. Other actors include statutory bodies such as the Kenya Veterinary Board (KVB), which regulates delivery of veterinary services by individuals and institutions; the Pest Control Product Board (PCPB), which regulates the importation, manufacture and use of pesticides; and the Pharmacy and Poisons Board (PPB), which controls the pharmacy profession and the trade in drugs and poisons in Kenya (Table 1). The legal

framework defines the roles of each actor, the qualifications for registration, the requirements for the licensing of premises, the ownership of business trading in medicines, the requirements for the registration, manufacturing, importation, distribution, sale and prescription of medicines and outlines the penalties for contravening each of the requirements of the laws (Table 1).

4.1.1 Disease control

Under the Animal Diseases Act (CAP 364), the DVS maintains a list of notifiable diseases. According to the OIE, a notifiable disease is a disease listed by the veterinary authority (DVS) that should, as soon as detected or suspected, be brought to the attention of this Authority in accordance with national regulations (Animal Diseases Act). The OIE maintains a list of all notifiable diseases. There are many other diseases of livestock that are not notifiable, but are economically important, and have to be controlled to increase livestock productivity and income.

The animal owner has an important role in disease diagnosis, prevention and control. Under the Animal Diseases Act, every person having in his possession an animal infected with a notifiable disease, or suspected of being infected with a notifiable disease, shall separate that animal from other animals and forthwith give notice of the outbreak to the nearest veterinary officer. The veterinary officer responds by instituting appropriate measures to control the outbreak and prevent its spread and may require the person having the animal in question to submit, within a period of not more than 24 hours, specimens for testing to ascertain the existence and nature of the notifiable disease.

Depending on the nature of the disease (ease of spread), the DVS may impose quarantine and movement control to minimize spread. After clinical diagnosis, veterinarians and veterinary para-professionals make decisions on case management and administer appropriate treatments using registered drugs. Only registered veterinarians are permitted to issue prescriptions for the treatment of animals.



Treatments and vaccinations are key strategies for disease prevention and control (Table 1). Vaccination is the administration of biological products to prevent disease from a corresponding disease-causing agent. The DVS gives guidelines for disease prevention and control using vaccines. The treatment of animals can only be carried out by persons registered by the KVB. Registered veterinary surgeons can offer all forms of treatments (prescription, medication, diagnosis, etc.). However, veterinary para-professionals can only offer the treatments listed in Annex 7. The criteria for the separation of services offered by veterinarians and veterinary para-professionals are based on the type of medical intervention and the type of medicine, not on the disease or the species of animal. Registered drugs that are listed in CAP 244 as Part I poisons (which includes antibiotics and vaccines) require prescription by registered veterinary surgeons (see section 4.1.2) and can only be administered by veterinarians or veterinary para-professionals under supervision (Annex 7). Drugs listed as Part II poisons do not require prescriptions. The DVS may prohibit the use of any vaccine or drug for the treatment of animal disease in Kenya. Mass vaccinations to control notifiable diseases are conducted by the Department of Veterinary Services. The Director may prescribe fees and payments for drugs and vaccines supplied by the Department. Occasionally, the DVS contracts members of the Kenya Veterinary Association to vaccinate livestock within specific regions to control one or more diseases. Registered veterinary practices carry out small-scale vaccinations, mostly for the control of poultry diseases. Although drugs and vaccines for the treatment of animal diseases should only be purchased on presentation of a prescription (see section 4.1.2), in practice, livestock owners can easily purchase drugs and vaccines from manufacturers, distributors and retailers and administer them to livestock on their own or with the assistance of veterinary para-professionals or unqualified persons (Annex 7).

Clinical diagnosis is a critical step in the rapid management of animal diseases (Table 1). This is commonly carried out by veterinarians and veterinary para-professionals. The use of field diagnostic kits with high sensitivity and specificity would greatly improve disease diagnosis and treatments. However, field diagnostic kits for the detection of livestock diseases by the veterinary services are not currently in use in Kenya. Such kits have had limited use only during the training of field veterinarians in the early detection of Highly Pathogenic Avian Influenza as part of emergency preparedness. Agro-vet shops operated by

veterinarians and veterinary para-professionals offer limited diagnostic services for poultry diseases. By law, diagnostic kits have to be registered by the PPB, and the DVS has to issue import permits. The confirmatory laboratory diagnosis of field samples should be done by regional veterinary investigation laboratories, the Central Veterinary Laboratory at Kabete, and by small-scale private veterinary laboratories. Unfortunately, veterinary laboratory diagnostic services are inadequate and most treatments are based on clinical diagnosis.

Early detection of sick animals and reporting to veterinary services is enhanced through public awareness by extension services. Public awareness, including training and sensitization, is conducted mostly by technical staff in the Departments of Livestock Production and Veterinary Services and by NGOs in the livestock sector. The DVS, through print media and gazette notices, also creates public awareness of the occurrence of outbreaks of notifiable diseases and may impose movement restrictions and closure of livestock markets to minimize disease spread.

4.1.2 Registration and sale of livestock health products

The Pharmacy and Poisons Act (CAP 244) establishes the Pharmacy and Poisons Board (PPB) under the Ministry of Health. The PPB has several functions, including the registration of pharmacists; the registration of drugs; the regulation of the manufacture and importation of drugs; the licensing of wholesalers and retailers of drugs; the licensing of premises authorized to store and sell drugs; the appointment of inspectors to supervise compliance with regulations for the sale of drugs; and the maintenance of a list of poisons that is authorized by the Minister for Health.

It is illegal to import, manufacture for sale or sell any drug in Kenya, unless that drug has been registered in accordance with the provisions of the Pharmacy and Poisons (Registration of Drugs) rules of CAP 244 (Table 1). The application for the registration of a drug can only be made by (i) the license or patent holder; (ii) the manufacturer; or (iii) an authorized local technical representative (LTR) of the manufacturer or license/patent holder. The application fee for the registration of drugs imported into Kenya is US\$1,000 and US\$500 for locally-manufactured drugs. The registration of medical devices, including diagnostic kits, costs US\$20. Though the average timeline for the registration of drugs is twelve months, and for medical devices three months, this is never the case and the registration of veterinary drugs and vaccines takes longer.



For instance, since 1993, the PPB has only registered two vaccines from the only local manufacturer of veterinary vaccines in Kenya. This could be a consequence of gross under-representation of the veterinary profession in the PPB, and thus an inadequate capacity to process applications for the registration of products for veterinary use. The validity of the registration of drugs and medical devices is five years, with an option for renewal. The Board maintains a list of registered products for veterinary use (www.pharmacyboardkenya.org).

It is an offence to sell pest control products that are not registered by the Pest Control Product Board (PCPB). Products for the control of animal pests are registered by the PCPB, established under the Pest Control Products Act (CAP 346; Revised 2012). The Act regulates the importation, exportation, manufacture, distribution and use of products for the control of pests of animals. For products to be registered for pest control, they must meet the requirements of the Cattle Cleansing Act (CAP 358). The registration of pest control products costs 30,000 shillings and is valid for a renewable period of three years. Premises for distribution, wholesale or retail, must be licensed, at a fee of 4,000 shillings, payable to the Board. Legal notice 145/1984 CAP 346 outlines the specific requirements to be met by premises handling pesticides in order to be licensed. The Pest Control Product Board licenses the sale of pest control products by veterinarians and veterinary para-professionals, as well as by any person knowledgeable about the efficacy, uses, handling precautions and shelf life of the products. Most of the pest control products are sold through agro-vet shops that are widely distributed throughout the country. The purchase of pest control products does not require prescription from a veterinary surgeon.

The Pharmacy and Poisons Act classifies drugs into two categories, as Part I and Part II poisons. The Part I poisons (including antibiotics and vaccines) consists of those poisons which, subject to the Act, are not to be sold except by authorized sellers of poisons (registered pharmacists) or by licensed wholesale dealers or retailers. No person (individually or corporate body) other than a registered pharmacist can carry on the business of a pharmacist and no person shall carry on the business of a pharmacist except in premises registered in accordance with CAP 244. In a partnership or a limited company manufacturing, distributing or retailing drugs, a registered pharmacist must be the majority shareholder. Any application for the registration of premises for the retail sale of drugs must indicate the name of a registered pharmacist who will be responsible for the business. The premises for the storage of drugs are inspected before the issuance of a license. The premises should have facilities for the storage of drugs and vaccines that require refrigeration or freezing. To sell drugs, an annual practice license of 2,500 shillings and a premises registration fee of 5,000 shillings have to be paid to the PPB.

Pharmacists registered by the PPB are the only authorized sellers of drugs listed as Part I poisons and can only sell to any person or institution in possession of a prescription from a veterinary surgeon. Veterinarians registered by the KVB are only allowed to keep limited stocks of Part I drugs for their own use while treating animals, but are not allowed to sell them. Any person can apply to the Board for a license to sell Part II poisons, which include registered pest control products such as those used in tick control. Under CAP 244, agro-vet shops, unless managed by a registered pharmacist, are not authorized to sell drugs listed as Part I poisons. However, due to weak inspection procedures by the PPB, most agro-vet shops stock drugs listed as Part I poisons and sell them to livestock owners without any prescription. The prohibition of registered veterinary surgeons from selling Part I poisons has created a lot of acrimony with the pharmacists. The VSVPP Act of 2011 has made provision for the establishment of a directorate of veterinary medicines to regulate the manufacture, importation, exportation, registration, distribution, prescription and dispensing of veterinary medicines and poisons. This will allow the participation of registered veterinary surgeons and veterinary para-professionals to sell veterinary drugs to livestock owners.

The Pharmacy and Poisons Board, the Pest Control Product Board and the Kenya Veterinary Board have inspectors who supervise compliance with the requirements of the laws and, in case of contravention, have the power to arrest the offenders for prosecution in a Court of Law. However, the Boards are faced with inadequate human and financial resources and do not provide effective field supervision to ensure that only registered livestock health products are being sold to animal owners by registered animal health service providers. As a result, many agro-vet shops that do not have registered pharmacists sell Part I poisons and also sell drugs that are not registered by the PPB or the PCPB. Fake products are available in the market from itinerant traders. Due to weak vigilance after the registration of drugs, cheaper fake products of doubtful quality are illegally imported into the country and sold to livestock owners. The sale of such products is rampant amongst pastoralists who, due to their low level of literacy, buy drugs based on packaging and low prices.



The DVS has powers under the Animal Diseases Act to prohibit the use of a vaccine or drug for the treatment of animal disease in Kenya and it is an offence for any person to knowingly supply, sell, purchase, obtain or use any prohibited vaccine or drug for the treatment of animals.

4.1.3 Registration of animal health service providers

A person practices as a veterinary surgeon if he/she engages in (a) the prevention of an infectious or organic disease or pathological condition; (b) the performance of a surgical operation on an animal; (c) the dispensing or administration of veterinary medicines for animals; (d) the giving of any treatment, advice, training, research, consultancy services, diagnosis or attendance and other related veterinary services. No person shall practice as a veterinary surgeon or a veterinary paraprofessional unless he is registered and licensed by the Kenya Veterinary Board under the VSVPP Act.

The KVB is established by the VSVPP Act under the Ministry of Agriculture, Livestock and Fisheries, and has the mandate to exercise general supervision and control over the training, business, practice and employment of veterinary surgeons and veterinary para-professionals. The Act defines the qualifications required for registration as a veterinary surgeon or as veterinary para-professional and makes provision for their registration.

A person shall be qualified to be registered as a veterinary surgeon if he is a citizen of Kenya and holds a degree in veterinary medicine from a University recognized in Kenya, has served an internship of not less than twelve months under a veterinary surgeon with not less than five years' standing and is a member of a registered professional association representing the interests of veterinary surgeons. A person shall be qualified for registration as a veterinary paraprofessional if the person is a citizen of Kenya and has successfully completed a post-secondary school training course in animal health science lasting two years or more at an institution approved by the Board and has a certificate, diploma or degree and has served an internship of not less than twelve months under supervision of a registered veterinary surgeon. Veterinary para-professionals are permitted to offer services listed in the Second Schedule of the VSVPP Act (Annex 7).

In its Second Schedule (Annex 7) the VSVPP Act specifies the category of services that can be offered by veterinary para-professionals and unqualified persons. Such services include parasite control in animals, the collection of samples for diagnosis and extension services to farmers and community members under delegated responsibility, as well as the closed castration of cattle under six months of age. Animal owners and unqualified persons over the age of eighteen years can render treatments in an emergency for the purpose of saving

life or relieving pain, provided the case is handed over to a qualified person for follow-up. A person who practices veterinary medicine or surgery without having been registered commits an offence and shall be liable, on conviction, to a fine not exceeding 100,000 shillings, or to imprisonment for a term not exceeding twelve months, or to both.

The administration of injectable medications by veterinary para-professionals can only be carried out under the responsibility or direction of a veterinary surgeon. The criteria for medication are not based on the disease or the species, but rather on the type of drug (Part I poison), the route of administration (injection), and the complexity of the surgical operation. Veterinary surgeons are required to issue prescriptions for the purchase of drugs listed as Part I poisons, offer medication and supervise veterinary para-professionals when they offer treatments.

No organization (including NGOs) or institution shall offer animal health services unless it is registered and issued with a licence by the Board and has a registered veterinary surgeon in its employment in charge of animal health and welfare services. For registration, such an organization or institution must pay 1,000 and 100,000 Kenya shillings, respectively, as an application fee and a one-off license fee, together with an annual inspection fee of 30,000 shillings.

The Board registers, licenses, controls and regulates veterinary practice, laboratories and clinics and issues permits to private veterinary practitioners. The Board has over 2,000 registered veterinary surgeons and over 4,000 registered veterinary para-professionals. Registered veterinarians and veterinary para-professionals in the public sector are the principal actors in delivery of livestock health services, whilst the distribution and retail of livestock health products is by the private sector.

Every registered person shall pay the Board an annual retention fee in such amount as the Board may, from time to time, prescribe. Every registered veterinary surgeon and veterinary para-professional is required to take out an annual licence before engaging in private practice. Registered veterinary surgeons and veterinary para-professionals in the Veterinary Department of the Government, livestock-based research organizations and the Faculty of Veterinary Medicine of any University in Kenya are exempted from an annual licence so long as they are working under a superior officer who is a registered veterinary surgeon.

The KVB undertakes inspectorate services to ensure compliance with ethical, licensing and technical standards in service delivery. It is an offence for any unregistered person to provide animal health services for a fee. Community-based animal health workers are not recognized by law as actors in livestock health service delivery.



Table one: FRAMEWORK FOR DELIVERY OF LIVESTOCK HEALTH PRODUCTS AND SERVICES IN KENYA

Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Registration of livestock health products (drugs, vaccines, and diagnostic kits) and pest control products.	Application for registration can only be made by: • license/patent holder; • manufacturer; or • a local technical representative of the license/patent holder or the manufacturer.	Registration of veterinary drugs is provided for under CAP 244, specifically the Pharmacy and Poisons (Registration of Drugs) Rules. Registration of pest control products is carried out by the Pest Control Products Board under CAP 346. Products must meet the requirements of the Cattle Cleansing Act CAP 358 such efficacy and safety and must be authorized by the DVS before registration by the PCPB.	Application fees for registration: drugs imported into Kenya - U\$\$1,000; locally-manufactured drugs - U\$\$500; locally-manufactured vaccines - U\$\$1,000; medical devices, including diagnostic kits - U\$\$20. Average timeline for registration of drugs is 12 months; for medical devices is three months. The validity of registration of drugs and medical devices is five years, with an option for renewal. Fee for registration of pest control products is 30,000 shillings and validity is for three years. The DVS can issue authorization for sale of unregistered products for use in Kenya to prevent and control animal diseases.	It is illegal to sell a drug that is not registered by the PPB or the PCPB. Enforcement of sale of registered livestock health products by PPB inspectors is very weak, hence unregistered products, fake or expired products are in the market and Part I poison products are sold by unauthorized persons and in premises that are not registered by the PPB. Registration of locallymanufactured vaccines is very slow and since 1993 the PPB has only registered two vaccines from the largest local manufacturer of veterinary vaccines. KVB is working towards the establishment of a veterinary medicines directorate under the VSVPP Act of 2011. This will improve registration and regulation of livestock health products and authorize veterinarians and veterinary para-professionals to distribute and sell veterinary medicines. Unregistered veterinary vaccines are used in Kenya with permission from the DVS. However, such vaccines cannot be exported.
Importation of drugs, vaccines and diagnostic kits.	Authorized wholesale dealers and seller of drugs.	Permits for importation of registered drugs, vaccines and medical devices (diagnostic kits) are issued by the Pharmacy and Poisons Board (PPB). The PCPB issues permits for the importation of pesticides to control animal pests. The DVS, under the Animal Diseases Act, issues permits for the importation of vaccines and authorizes their use in the country. Vaccine importers have to get permits from the DVS and the PPB.	Although the law requires that only registered products are imported into the country, the availability of unregistered products of low quality made in India and China implies the presence of illegal imports. Fake products are also available in the market and are alleged to originate from neighbouring countries.	Most of the veterinary drugs, vaccines for poultry and all diagnostic kits used in Kenya are imported. The enforcement of the PPB is weak. Cross-border trade is very difficult to control and unregistered products can enter the country through the porous border from neighboring countries.



Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Distribution and sale of veterinary drugs, vaccines and diagnostic kits (Who is allowed to prescribe, administer and/or sell.)	Only pharmacists registered by the PPB are the authorized distributors and sellers of Part I poison products. This must be done in premises licensed by the PPB and with a registration certificate of the pharmacist in charge displayed (4.1.2). Persons licensed by PCPB to sell pest control products (4.1.2).	The PPB issues permits and licenses for sale of Part I and Part II poisons by authorized persons (registered pharmacists). Part I poisons (including antibiotics and vaccines) are only sold through registered premises by registered pharmacists on presentation of a prescription from a registered veterinary surgeon. Any person can be registered and licensed by the PPB to sell Part II poison products. Premises must be inspected and certified by either the PPB or the PCPB as suitable for storage (adequate space, safe custody and not mixed with food) and sale registered products. Veterinarians registered by the KVB are only allowed to keep limited stocks of Part I drugs for their own use while treating animals, but they are not allowed to sell them.	Although the law requires the presence of registered pharmacists in premises selling Part I poisons, the practice is that this is rarely adhered to; many agro-vet shops selling such products have no registered pharmacists. Nearly all veterinary drugs can be purchased by animal health service providers and farmers without prescription.	In human health, most people buy antibiotics from pharmacy outlets without any prescription. This practice has been extended to the livestock sector by animal owners and veterinary drug shops. The VSVPP Act of 2011 authorizes the Cabinet Secretary in charge of Agriculture to establish a veterinary medicines directorate to regulate the registration, manufacture, distribution and sale of veterinary medicines. This will address the current tension between the PPB and the KVB and also allow registered veterinary surgeons to distribute and dispense veterinary medicines.
Sale of registered pesticide products (Who is allowed to prescribe, administer and/or sell.)	Persons knowledgeable about the efficacy, use, safety precautions and shelf life of pest products.	The PCPB issues permits to persons who qualify to stock and sell pest products in licensed premises (Pest Control Products Act). Under the Cattle Cleansing Act, the DVS issues policy guidelines on the products to be used for tick control and the administrative regions where such products are to be used. The purchase of registered pest control products does not require prescription from veterinary surgeons.	Privatization of tick control weakened the regulation of the use of tick control products. The unregulated use of pesticides has the potential to lead to the emergence of tick resistance. The sale of pesticides for tick control is uncontrolled and products can be bought from hardware shops.	Pest control products are the only products that can legally be sold in outlets with no registered pharmacist. The rampant misuse of pest control products leads to the emergence of tick resistance and a resurgence of tick-borne diseases, thus eroding livestock productivity.



Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Medication – treatment	Registered veterinary surgeons (4.1.3). Registered veterinary para-professionals under supervision of a registered veterinary surgeon (Annex 7). Animal owners (Annex 7). Unqualified persons are allowed to offer emergency treatments and report to a veterinarian (Annex 7).	The Veterinary Surgeons and Veterinary Para-professionals Act (VSVPP) of 2011 specifies the qualification for registration as a veterinary surgeon or as a veterinary para-professional (4.1.3). Only registered veterinary surgeons can give prescription for treatments. Annex 7 lists the services to be offered by veterinary para-professionals and unqualified persons. Criteria for medication are based on the type of medicine and medical intervention and not on the disease or the species of animal (4.1.3 and Annex 7). Requirements for distribution and sale (see above). Organizations or institutions offering animal health services such vaccination must be registered and licensed by the KVB and must employ a registered veterinary surgeon to be in charge of animal health and welfare.	In rural areas, access to veterinary services from registered veterinary surgeons is poor. Hence, most treatments are offered by registered veterinary paraprofessionals, livestock technicians (not trained in animal health), community-based animal health workers in pastoral areas and animal owners. In practice, the para-vets often carry out vaccinations without supervision. Animal owners freely access prescription drugs without prescription and treat their animals, or get para-professionals to do it.	The long turnaround time for diagnosis in government veterinary laboratories has made livestock farmers and field veterinarians reluctant to submit samples for laboratory confirmatory diagnosis before treatment. A few private veterinary laboratories have appeared, but cannot fill the gap.



Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Vaccinations	Department of Veterinary Services. Registered and licensed veterinary surgeons. Veterinary para-professionals under supervision of a veterinary surgeon. Animal owners are allowed to treat their own animals. Treatment includes vaccination. Paravets employed by the Government or registered veterinarians have delegated authority to vaccinate without supervision (Schedule II of the VSVPP Act)	The DVS, under the Animal Diseases Act, has to authorize the importation and use of vaccines in disease control and can also authorize the use of vaccines that have not been registered by the PPB. Vaccines have to be registered (Pharmacy and Poisons Act(Cap 244). As Part I poison products, vaccines can only be sold by registered pharmacists in premises licensed by the PPB upon presentation of a prescription from registered veterinary surgeon. The DVS also issues policy guidelines on the use of vaccines to control trans-boundary animal diseases (such as PPR, FMD, CBPP). Veterinary surgeons give advice on vaccination and administer injectable vaccinations. Vet paraprofessionals can offer services listed in Annex 7. Organization or institutions offering animal health services such as vaccination must be registered and licensed by the KVB and must employ a registered veterinary surgeon to be in charge of animal health and welfare.	Individuals and institutions can buy vaccines from manufacturers, distributors and retailers without prescription of veterinary surgeons. Community-based extension officers are used in the vaccination of poultry. Through an EU funded project, Kenya Arid and Semi-Arid Lands (KASAL), the Kenya Agriculture Research Institute has worked with communities to identify individuals for two weeks of training as community-based extension officers for indigenous poultry management and control of Newcastle disease in several districts in the eastern province. Once trained, they buy vaccines from agro-vet shops in Nairobi, store it in rural shops that have refrigeration and vaccinate indigenous chickens at a fee of five shillings per bird. With the availability of the thermo-stable Newcastle 12 vaccine, the community-based vaccination has gained popularity with NGOs. Most poultry farmers decide when to vaccinate. Vaccines are readily available to farmers.	Occasionally, the DVS contracts the KVA to undertake mass vaccination in areas selected by DVOs, using vaccines supplied by the Department of Veterinary Services. The KVA charges the livestock owners for the vaccinations.
Clinical diagnosis and field diagnostics.	Veterinary officers in the Department of Veterinary Services. Registered veterinary surgeons and veterinary para-professionals.	Diagnostic kits are registered by the PPB as medical devices. Under the Animal Disease Act, veterinary officers obtain specimens from sick animal to ascertain the nature of a notifiable disease. Veterinary laboratories in the Department of Veterinary Services provide laboratory confirmatory diagnosis to guide treatments and vaccination.	Clinical diagnosis is the principal form of diagnosis used in the treatment of sick animals. Public sector veterinary laboratories are not efficient, due to inadequate financial resources. In rural areas, access to veterinarians is poor, inspection by the KVB is weak; thus an unqualified person can provide clinical diagnosis and treatment in contravention of the VSVPP Act.	The Government does not provide adequate funding for disease prevention and control. The KVB does not have adequate human and financial resources for inspectorate services to ensure unqualified persons do not illegally treat animals. The planned decentralization of the KVB to open branches in strategic areas of the country will help to reduce incidence of unqualified persons offering services they are not supposed to do (Annex 7).



4.2 Uganda

The delivery of livestock health products and services is regulated by the Animal Diseases Act (CAP 38), the Veterinary Surgeons Act (CAP 277) and the National Drug Policy and Authority (NDP/A) Act CAP 206 of 1993. The role of the actors in the delivery of livestock health products and services is summarized in Table 2.

4.2.1 **Disease control**

Under the Animal Diseases Act (CAP 38), the Commissioner of Livestock and Entomology maintains a list of notifiable diseases. According to the OIE, a notifiable disease is a disease listed by the veterinary authority (DVS) that, as soon as detected or suspected, should be brought to the attention of this Authority in accordance with national regulations (Animal Diseases Act). The OIE maintains a list of all notifiable diseases. There are many other diseases of livestock that are not notifiable but are economically important, and have to be controlled to increase livestock productivity and income.

The Animal Diseases Act in Uganda is very similar to the one in Kenya and every person having in his possession an animal infected with a notifiable disease or suspected of being infected with a notifiable disease shall separate that animal from other animals and forthwith give notice of the outbreak to the nearest veterinary officer. The veterinary officer responds by instituting appropriate measures to control the outbreak and prevent its spread and may require the person having the animal in question to submit, within a period of not more than 24 hours, specimens for testing to ascertain the existence and nature of the notifiable disease. All disease outbreaks reported to a veterinary officer must be reported to the Commissioner of Livestock and Entomology. Depending on the nature of the disease (ease of spread), the Commissioner may impose quarantine and movement control to minimize spread. With devolution, the scaling down of the civil service and the privatization of clinical services, several cadres of staff that were retired from the MAAIF started selling veterinary drugs and offering treatments.

In pastoral areas, the main actors in the treatment of animals include herdsmen, animal owners, community animal health workers, drug shops, traders, animal health assistants, government veterinarians (DVO), private veterinarians and non-governmental organizations. The herdsmen report disease outbreaks to the livestock owners, who then buy drugs from drug shops and treat the sick animals. They seek the services of CAHWs when the case fails to respond. The CAHWs can buy

drugs from drug shops but, in some cases, NGOs give drugs to CAHWs who in turn sell the drugs to the animal owners at subsidized prices. In difficult cases the CAHWs may consult veterinarians or totally give up, thereby forcing the animal owner to sell the sick animal. Animal owners also use traditional remedies to treat sick animals and only seek help from CAHWs or veterinarians when the sick animals fail to recover quickly. Non-governmental organizations train CAHWs for three months on basic animal health services such as the spraying of animals for tick control, deworming and the detection of sick animals. However, most NGO projects are short lived (Ilukor et al.).

In intensive agricultural areas, the key actors in disease control include the animal owner who reports disease outbreaks to para-professionals (animal health technicians and livestock officers), private veterinarians, government veterinarians and drug shops. Animal owners very rarely treat their animals, unless the case is not complicated and they have the appropriate drug. The para-professionals are readily available and play an important role in offering treatment. They work very closely with private veterinarians, but poorly with government veterinarians who, in most cases, work with the better-paying National Advisory Services and have no incentives to be involved in disease control.

Vaccines for epidemic diseases are always procured by the Government, and occasionally by NGOs and the UN FAO through the Government. The Government, through MAAIF, gives the vaccines free of charge, but does not always give the local government logistical support for conducting vaccination campaigns. The NGOs step in and provide transport, fuel, training and mobilization of CAHWs and livestock farmers. DVOs provide coordination and supervisory roles, as vaccination is carried out by CAHWs.

4.2.2 Registration and sale of livestock health products

The National Drug Authority (NDA) was established under the National Drug Policy and Authority (NDP/A) Act CAP 206, 1993, under the Ministry of Health. The National Drug Policy ensures the availability of essential, efficacious and cost-effective drugs to the entire population of Uganda at all times, in order to provide satisfactory healthcare and safeguard the appropriate use of drugs. The NDA is charged with the responsibility of implementing the National Drug Policy and, in particular, of dealing with the development and regulation of the pharmacies and drugs in the country,



approving the national list of essential drugs, registering drugs, issuing licenses for the wholesale and retail trade of drugs and controlling the importation and sale of pharmaceuticals. No person or body shall import drugs into Uganda without a license from the NDA and no person shall import or sell any drug unless it appears in the national formulary. However, a drug that does not appear in the national formulary may be imported and sold after authorization by the drug authority, in emergency or extraordinary circumstances. This provision has been used to give temporary authorization for the importation and use of the ECF vaccine.

Drugs listed under the First, Second and Third Schedules of the Act are Class A, B and C restricted drugs that can only be sold by authorized sellers and in licensed premises. The sale of restricted drugs can be undertaken by licensed persons, under the immediate supervision of a pharmacist. In the case of a corporate body or a partnership, at least one of the directors or partners must be a pharmacist resident in Uganda. The NDA can license a person to sell, by retail, restricted drugs other than Class A or B drugs. Pharmacists are registered by the Pharmacy Board under the Pharmacy and Drugs Act (Cap 280 of 1971), but licenses for the business of pharmacy are issued by the NDA.

Application for the registration of a drug or vaccine can only be made by the patent holder, the manufacturer or a local technical representative (LTR) of the manufacturer or patent holder. The local capacity for the manufacturing of veterinary drugs, including vaccines, is weak and most of the drugs are imported. The registration of drugs is, therefore, mostly done by LTRs appointed by foreign manufacturers to import and distribute veterinary drugs. The local company or LTR registering the drugs must have legal authorization to take full responsibility for the product on behalf of the applicant, and be answerable to the NDA. The distributor sells veterinary drugs through retail pharmacies licensed by the NDA. Registration of veterinary drugs is slow and since 1993, the NDA has registered only 300 products for veterinary use.

4.2.3 Registration of animal health service providers

The Veterinary Surgeons Act (CAP 277) prohibits any person who is not registered by the Uganda Veterinary Board (UVB) from practicing as a veterinary surgeon or becoming a practitioner of veterinary surgery. The Act defines the practice of veterinary surgery to mean the performance of any operation and the giving of any treatment, advice, diagnosis or attendance in respect of an animal for gain or reward. The UVB is established

by the Veterinary Surgeons Act and is under the Ministry of Agriculture, Animal Industry and Fisheries (MAAIF). The Act makes provision for the registration of practitioners of veterinary surgery and for other matters connected with and incidental to the practice of veterinary surgery. The UVB is currently very weak, and thus not in a position to effectively regulate animal health service delivery.

Enacted in 1958, the Veterinary Surgeons Act does not recognize the role of veterinary para-professionals in animal health service delivery. However, the Act makes provision for the licensing of persons who are not trained in veterinary medicine to practice veterinary surgery in areas of Uganda where there is an insufficient number of registered veterinary surgeons or licensed veterinary practitioners. Such persons may include livestock officers and trained animal health technicians (diploma holders). In certain instances, the MAAIF Minister is mandated to authorize the use of community-based animal health workers (CAHWs). This prerogative has been exercised in the Karamoja area.

The National Policy for the delivery of veterinary services (2001) identifies disease control actions that can be taken by the central Government, the local government and the private sector. The policy provides for the central Government to contract out some of the public good services that the private sector can effectively deliver to promote private veterinary practice (e.g. mass vaccination) and encourage NGOs and other organizations to support the establishment of private veterinary practices through the promotion of community-based animal health programs. The central Government ensures the enforcement of legislation regulating veterinary service providers through the Uganda Veterinary Council.

Non-governmental organizations can reach remote areas and deliver livestock health products through CAHWs. The NGOs can access all veterinary products from distributors and retailers and use CAHWs, under the supervision of District Veterinary Officers, to offer treatments. Veterinary vaccines from the central Government are channeled through the DVOs. In most cases, the central Government does not provide funds for vaccination campaigns and the NGOs have to step in to fund transport and logistical support. Unlike in Kenya, where the VSVPP Act makes provision for the registration and licensing of NGOs and other institutions delivering animal health, the Veterinary Surgeons Act of Uganda does not make such provision. It was not possible to identify the policy under which the NGOs deliver animal health services. The Act also excludes veterinary para-professionals (livestock officers and animal health assistants) trained in animal health.



Table two: FRAMEWORK FOR DELIVERY OF LIVESTOCK HEALTH PRODUCTS AND SERVICES IN UGANDA

Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Registration of veterinary medicines, vaccines and diagnostic kits.	Application for registration can only be made by: • license/patent holder; • manufacturer; or • a local technical representative of the license/patent holder or the manufacturer.	National Drug Authority established under the NDA/A Act of 1993. Guidelines for registration of vaccines are available from the NDA.	Information gathered during the study indicates that some unregistered products are available in the market.	There is a perception in the livestock sector that the NDA being under the Ministry of Health does not give priority to the registration of veterinary medicines. The NDA has registered only 300 veterinary drugs since 1993. The position of the Uganda Veterinary Association is that the veterinary representation in the NDA should be increased so that regulation of veterinary drugs is improved.
Importation of veterinary drugs, vaccines and diagnostic kits.	Companies with registered pharmacists.	The National Drug Authority, established under the NDA/A Act of 1993, issues import permits. The drug must appear in the national formulary. Pharmacists are registered by the Pharmacy Board under the Pharmacy and Drugs Act (CAP 280). The Commissioner of Livestock and Entomology, under the Animal Diseases Act, authorizes the importation of vaccines.	Information gathered during the study indicates that some unregistered products, usually of low quality and cheaper, are available in the market.	The NDA lacks the adequate human, financial and physical capacity to ensure that only registered drugs are imported into the country. Although the ECF vaccine is not registered, the NDA has given temporary authorization for its importation and use to AFRISA. The vaccine is distributed by two companies licensed by the NDA.
Distribution and sale of veterinary medicines, vaccines and diagnostic kits.	Registered pharmacists.	The NDA issues licenses to persons and corporate bodies qualified to store and sell restricted products (NDA Act – Schedule 1, 2 & 3). The sale of restricted products, such as antibiotics, requires prescription from registered veterinary surgeons. Premises for sale of drugs must be inspected and licensed by the NDA	The main drug distribution centers are in urban areas. Though the law requires presence of registered pharmacists in premises, selling restricted products (Classes A, B and C) this is not always the case. Pharmacists are mainly in urban pharmacies and the drug shops found in the rural areas have no registered pharmacists. Although restricted drugs can only be sold under prescription, this requirement is not strictly adhered to and animal health service providers and farmers can freely purchase drugs without prescription. Livestock vaccines for major transboundary diseases are procured and regulated by the central government and the private sector is reluctant to stock them for the vaccines could expire in their stores if the government failed to authorize their use within the shelf life period. Poultry vaccines are distributed by the private sector in premises licensed by the NDA.	The NDA lacks adequate human, financial and physical capacity to ensure that only registered drugs are imported in to the country. The Uganda Veterinary Board that would regulate veterinary practice is not functional. There is a perception amongst the veterinarians and livestock owners that pharmacists do not provide additional value in selling of veterinary products since they do not have training in veterinary medicine. No information on use of field diagnostics was available.



Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Sale of registered pesticides.	Registered veterinary surgeons.	NDA	The control of ticks and tick-borne diseases is a function of the local government and the private sector. The selection of pesticides for tick control and their sale and use are not well coordinated or regulated. Information gathered during the study indicates that sale and use of pesticides of low quality is common in rural areas.	The control of ticks and tick-borne diseases has broken down and livestock farmers have petitioned central Government to intervene.
Treatment (medicines).	Registered veterinary surgeons.	Registered veterinary surgeons, under CAP 277 (Act does not provide for the registration of animal health officers).	Although the Veterinary Surgeons Act only permits veterinary surgeons to offer treatments, in practice animal owners, CAHWs and animal health technicians do offer treatments in different parts of the country. The animal health technicians and private veterinarians offer their services in intensive livestock production areas. Animal owners freely access all medicines and treat their animals, or get para-professionals to do it. The Veterinary Surgeons Act has a provision for the UVB to license non-veterinarians to treat animals in areas of the country with inadequate numbers of registered veterinary surgeons. In remote pastoral areas, CAHWs have been legally authorized by the Minister to work with NGOs in animal health service delivery. Through community dialogue by NGOs, communities select trusted young people for a three-month training as CAHWs. The CAHWs can buy drugs from drug shops; in some cases, the NGOs supply them with drugs. The NGOs facilitate the CAHWs to vaccinate livestock, under supervision of the DVO. In pastoral areas, livestock owners prefer to initially treat animals using traditional medicine. They shift to modern medicine when animals fail to respond to traditional medicine, thus delaying effective treatment.	The Uganda Veterinary Board, which should be ensuring that only qualified and registered persons offer treatments, is not operational due to financial constraints. A high level of illiteracy amongst pastoralists and the low education of CAHWs lead to drug misuse – over-dosing or under-dosing and the use of the wrong drugs. CAHWs in the Karamoja pastoralist area are allowed by the MAAIF. There is a need for increased awareness of registered drugs to ensure that animal owners do not make choices on pricing alone.



Livestock health Actors Legal provision Practice in place Remarks products and with legal services recognition Vaccinations The Veterinary Central Government Devolution and the Veterinary Surgeons Act allows controls vaccination for privatization of clinical surgeons and services has weakened veterinary surgeons FMD, CBPP and rabies, animal health to vaccinate. Animal disease control in the country. assistants. but vaccines are not health technicians always available when Livestock farmers can do so under the needed. The private sector – are allowed to supervision of is not willing to procure only treat their veterinary surgeons. the vaccines without animals if they Vaccines have to be irrevocable contracts, choose to. since the vaccines have registered by the NĎA. a limited shelf life. The Commissioner Other veterinary vaccines of Livestock and are imported and Entomology decides distributed by the private the vaccines to be sector. Farmers buy used in disease vaccines without control. prescriptions, even though it is an offence. Although the ILRI ECF vaccine is not registered, the NDA has given temporary authorization for its importation and use. Livestock owners and animal health technicians vaccinate animals. ECF vaccination is carried out by networks of animal health technicians, under the supervision of veterinarians. In pastoral areas, CAHWs are facilitated by NGOs to vaccinate livestock, under supervision of DVOs. Diagnosis and Animal Diseases Act. The central and regional Point-of-care veterinary Registered diagnostics diagnosis using test kits is government veterinary veterinarians. field kits. laboratories are not not currently practiced. supported with adequate finances to offer confirmatory diagnosis. Private sector veterinary laboratories are not available.





4.3 Tanzania

The delivery of livestock health products and services is regulated by the Animal Diseases Act (No. 17 of 2003), the Veterinary Act (No. 16 of 2003) and the Tanzania Food, Cosmetics and Drugs Act (2003). The role of the actors in the delivery of livestock health products and services is summarized in Table 3.

4.3.1 Disease control

Animal diseases in Tanzania are controlled under the Animal Diseases Act (No. 17 of 2003) that came into effect on 30 January 2004. The Act makes provision for the control and prevention of animal diseases, for monitoring the production of animal products, for the disposal of animal carcasses and for other related matters. The Director of Veterinary Services, amongst other things: maintains a list of all notifiable diseases in the country; issues the official position on the method to be used in the diagnosis, control, treatment, disposal and quarantine for each notifiable disease; regulates the use of animal pesticides, vaccines and any other related products; and ensures the successful implementation of all provisions of the Animal Diseases Act. Animal owners have a legal duty to report diseases or deaths of animals to the nearest veterinarian or para-professional within 24 hours. The veterinarian or para-professional who receives notice of a disease outbreak must immediately take measures to control the disease (diagnosis, collection of specimens for testing, treatment, vaccination, movement control, quarantine) and report the matter to an Inspector (veterinarians or para-professionals appointed by the Minister for Livestock). During a disease outbreak, an Inspector may demarcate infected areas and buffer zones and mandate each animal owner in a buffer area to vaccinate all his animals, or carry out any other preventive measures against a disease under consideration. The Inspector collects regular specimens (blood or tissue) for the purpose of detecting or diagnosing disease and also to check the immune status of animals in the buffer zone (between infected and uninfected areas). The Minister prescribes compulsory disease control measures for all areas in the country, including specifying the measures to be taken by owners of animals, local government authorities, Inspectors and veterinarians.

The Tanzania Veterinary Laboratory Agency (TVLA), an Executive Agency of the Ministry of Livestock and Fisheries Development (MLFD) established under the Executive Agency Act CAP 245 (2009) on 11th July 2012 carries out: diagnosis and investigation of animal diseases and vectors; development and production of vaccines and other biologicals; and regulation of veterinary laboratories. The Agency operates in multiple sites in Tanzania.

4.3.2 Registration and sale of livestock health products

Registration of livestock health products is under the Tanzania Food and Drugs Authority (TFDA), established by the Tanzania Food, Cosmetics and Drugs Act of 2003. The Act provides for the efficient and comprehensive regulation and control of food, drugs, medical devices, cosmetics, herbal drugs and poisons and to provide for related matters. The Act regulates all matters relating to: the quality and safety of drugs and medical devices; the importation, manufacture, labeling, marking or identification, storage, promotion, selling and distribution of drugs and medical devices, or any materials or substances used in the manufacture. The TFDA approves and registers products, appoints inspectors and orders inspections of premises, as well as promoting the rational use of drugs and medical devices. No person shall manufacture drugs for sale, import, export or distribution, unless they have a license or permit to do so; only a registered pharmacist can hold the license or permit. In addition, no person shall test, register or use animal pesticides or animal chemicals for disease control in the country without the written permission of the Director in respect of that particular animal pesticide or animal chemical.

All drugs and medical devices for sale must be registered by the TFDA. The premises for manufacturing for selling or storing drugs must be inspected and, if appropriate, registered and licensed by the TFDA. A license or permit to sell drugs will be issued or renewed only if the person applying for or holding the permit or license is, or has, a registered pharmacist in control of the distribution of the drugs. A wholesale license or permit to sell veterinary drugs will only be issued or renewed if the person applying for, or holding, the permit or license is, or has, a pharmacist or veterinary surgeon in direct control of the distribution of veterinary drugs.



4.3.3 Registration of animal health service providers

The Veterinary Act (No. 16 of 2003) makes provision for the registration of veterinarians, the enrollment of para-professionals or the enlistment of para-professional assistants, for the establishment of the Veterinary Council of Tanzania (VCT) and for other matters incidental and connected thereto. The functions of the VCT include the registration of veterinarians, veterinary specialists and veterinary practice facilities; the enrollment of para-professionals and the enlistment of para-professional assistants; the regulation of veterinary practice; the exercise of effective disciplinary control over the professional ethics and conduct of veterinary practice; and the making of recommendations to the Minister on any matters relating to veterinary practice. A person qualifies for registration as a veterinarian if he/she has a veterinary degree recognized by the VCT.

A person shall enrol with the Council to practice as a para-professional if he/she has been awarded a diploma in animal health recognized by the Council. A person shall enlist with the Council to practice as a para-professional assistant if he/she has been awarded an animal health certificate recognized by the Council. An enrolled para-professional or an enlisted para-professional assistant shall at all times practice under the supervision of a registered veterinarian or a veterinary specialist. No person shall practice as a veterinarian, veterinary specialist, para-professional or para-professional assistant unless he/she has been registered, enrolled or enlisted, respectively. The Act allows the owner, a member of the household or a regular employee of the household to treat animals. The Act also lists the minor treatments and operations that can be given by persons that are not registered, enrolled or enlisted.





Table three: FRAMEWORK FOR DELIVERY OF LIVESTOCK HEALTH PRODUCTS AND SERVICES IN TANZANIA

Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Registration of veterinary drugs, vaccines and diagnostic kits.	Registered pharmacists or corporate bodies with registered pharmacists.	Food, Drugs and Cosmetics Act of 2003. Registration of drugs, vaccines and diagnostics is carried out by the TFDA. The Minister declares a list of drugs, medical devices or poisons that are classified as controlled drugs, prescription drugs and general sale drugs.	Information gathered during the study indicates that some unregistered products are available in the market.	There is a perception in the livestock sector that, because the TFDA is under the Ministry of Health, it does not give priority to the registration of veterinary medicines.
Importation of veterinary drugs, vaccines and diagnostic kits.	Companies with registered pharmacists.	Food, Drugs and Cosmetics Act of 2003. Pesticide Control Regulations of 1984. Tropical Pesticides Research Institute (TPRI) Act, No. 18, 1979.	Information gathered during the study indicates that some unregistered products, usually of low quality and cheaper, are available in the market. Inspectors appointed by the TFDA monitor the importation, distribution and sale of drugs.	
Distribution and sale of veterinary medicines, vaccines and diagnostic kits.	Registered pharmacists or, in the absence of pharmacists, veterinarians and para-professionals, can also sell veterinary drugs in registered veterinary facilities. A wholesale license or permit to sell veterinary drugs shall only be issued to a pharmacist or a veterinary surgeon in direct control of the distribution of veterinary drugs.	Food, Drugs and Cosmetics Act of 2003. No person shall manufacture for sale, sell, supply or dispense any drug, except under the immediate supervision of a registered pharmacist.	In pastoral areas, drugs are sold in drug shops that are not under the control of pharmacists. Animal owners freely access all medicines and treat their own animals, or get para-professionals do it.	The sale of veterinary medicines is not easy to regulate, especially in pastoral areas. The TFDA lacks adequate human, financial and physical capacity to ensure that only registered drugs are imported into the country.
Sale of registered pesticides.	Registered veterinary surgeons and veterinary para-professionals. Agro-vet shops.	Food, Drugs and Cosmetics Act of 2003. Pesticide Control Regulations of 1984. Tropical Pesticides Research Institute (TPRI) Act, No. 18, 1979.	The sale of pesticides for tick control is uncontrolled, and they can be bought from hardware shops.	Veterinarians can only sell pesticides in the absence of a registered pharmacist.



Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Treatment (medicines).	Inspectors appointed by the Minister, registered veterinarian, enrolled para-professionals and enlisted para-professionals assistants. Animal owners, members of the household or their employees.	Animal Diseases Act (2003), Veterinary Act, 2003. Enrolled para-professionals and enlisted para-professional assistants must at all times treat animals under the supervision of registered veterinarians. The Act specifies the minor treatments and operations that can be offered by persons who are not registered, enrolled or enlisted. The Act does not recognize the role of CAHWs in animal health service delivery.	Information gathered during the study indicates that treatments are offered by registered, enrolled or enlisted persons, as well as persons who have received only a few days' training in animal health. Though recognized by law, CAHWs offer treatments in pastoral areas of the country.	The VCT does not have adequate capacity to regulate animal health service delivery in the rural areas.
Vaccinations.	The Director of Veterinary Services decides which vaccines are to be used on animals. Veterinary Officers, private practitioners, para-professionals and animal owners.	Animal Diseases Act (2003).	The TVLA manufactures vaccines such as the thermostable I2 vaccine and distribute them through its zonal centers. The local governments get the vaccines from the TVLA zonal centers. Veterinarians, para-professionals and village vaccinators (trained for a few days to vaccinate chickens against Newcastle disease) vaccinate livestock based on the advice of local Inspectors (using epidemiological information on prevailing diseases). In poultry production, the owners decide when to vaccinate and which vaccines to use, and procure them from licensed commercial outlets. The Government contracts the private sector to import vaccines and conduct vaccinations in selected areas of the country. Animal owners can buy nearly all vaccines from legal or illegal outlets and decide when to vaccinate their animals.	The control of Newcastle disease using village-based vaccinators has greatly improved productivity of the poultry sector.
Diagnostics – field kits.	Registered veterinarians, enrolled para-professionals and enlisted para-professional assistants offer clinical diagnosis and collect specimens for laboratory diagnosis.	Diagnostic kits are registered by the TFDA as medical devices. The TVLA is established under the Executive Agency Act and offers diagnostic services to the public and the private sector at a fee.	Field diagnostic kits are currently not in use. The TVLA charges for all its diagnostic services.	



4.4 Malawi

The regulation of livestock health products and services in Malawi is through the Control of Animal Diseases (CAP 66.02 of 1967), the Veterinary Surgeons and Veterinary Para-professionals Act of 2001, and the Pharmacy, Medicines and Poisons Act of 1988. The role of the actors with legal recognition for the registration, distribution and sale of drugs, treatments, vaccinations and diagnosis is summarized in Table 4.

4.4.1 **Disease control**

The Department of Animal Health and Disease Control has only five veterinarians and, to cover for this shortage, has employed about 200 Area Veterinary Assistant Officers who have been trained on animal health and disease control for two years. The veterinary assistants collect disease surveillance information, treat sick animals and vaccinate livestock and are assisted in disease reporting by animal health surveillance assistants, key men or leading influential farmers. The animal health surveillance staff are trained on the job and form part of the national diseases surveillance network. They do not offer treatments or vaccinations. The veterinary assistants buy drugs and vaccines from veterinary pharmacies and drug shops.

The control of trans-boundary animal diseases, including FMD and CBPP, is carried out by the Government, free of charge. ECF is not considered a public good in Malawi and its control is not a high priority, even at farm level. Treatment and vaccination to control other notifiable diseases, as well as endemic diseases, is carried out by veterinary assistants. It was stated that in the rural areas, most of the veterinary assistants have abandoned animal production and extension services and have focused on private services that are more lucrative.

4.4.2 Registration and sale of livestock health products

It is an offense to sell any drug that is not registered under the Pharmacy, Medicines and Poisons Act of 1988. The registration of veterinary drugs is carried out by the Pharmacy, Medicines and Poisons Board, created under the Pharmacy, Medicines and Poisons Act of 1988 within the Ministry of Health. The Act provides for the establishment of the Board, the registration and disciplining of pharmacists, pharmacy technologists and pharmacy assistants, the licensing of traders in medicines and poisons and generally for the control and regulation of the profession of pharmacy in

Malawi and for matters incidental to or connected therewith. Only registered pharmacists can retail veterinary pharmaceuticals in premises that are registered and licensed by the Board. As in the other countries, veterinarians are only allowed to have small quantities of drugs for the treatment of animals, but cannot sell veterinary drugs. The veterinarians issue prescriptions for prescription-only drugs. However, due to the extremely low number of field veterinarians, the requirement for prescriptions is difficult to adhere to during the sale of drugs. However, the inspection of the quality of veterinary products available in the market is not adequate, and a wide range of products of inferior quality is in circulation. The Department of Veterinary Services maintains an inventory of vaccines that are in use in the country. AU-CTBBD is developing a new batch of ECF vaccine from master seed obtained from ILRI. This new ECF vaccine will be commercialized and distributed by various partners in Africa. This represents a good model for rhe commercialization of vaccines developed by international research institutes.

4.4.3 Registration of animal health service providers

The Veterinary Act establishes the Veterinary Board. However, due to inadequate human and financial capacity, the Board is not functional. There have only been eight veterinarians registered by the Board.

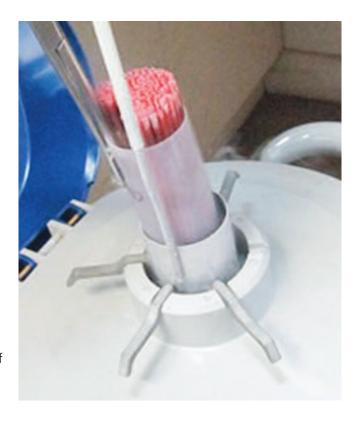




Table four: FRAMEWORK FOR DELIVERY OF LIVESTOCK HEALTH PRODUCTS AND SERVICES IN MALAWI

Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Registration of veterinary medicines, vaccines and diagnostic kits.	Registered pharmacists, Pharmacy, Medicines and Poisons Board register the products.	Pharmacy, Medicines and Poisons Act. It is an offense to sell products that are not registered by the Board.	Enforcement of drug regulations is weak and many unregistered products are available in the market.	The DVS advises the Pharmacy, Medicines and Poisons Board on the registration of veterinary drugs.
Importation of veterinary medicines, vaccines and diagnostic kits.	Registered pharmacists.	Pharmacy, Medicines and Poisons Act. The Pharmacy Board issues import permits for veterinary drugs. The DVS, under the Control of Animal Diseases Act, issues permits for the importation of vaccines.	Due to inadequate human and financial capacity, the importation of livestock health products is not well regulated.	There is no adequate capacity to monitor imported veterinary medicines and vaccines.
Distribution and sale of veterinary medicines, vaccines, and diagnostic kits.	Only registered pharmacists can sell veterinary medicines. A veterinarian is allowed to handle medicines in the normal course of his/her duties.	Pharmacy, Medicines and Poisons Act. Pharmacy Board registers premises and issues licenses for distribution and retail of livestock health products.	There are very few distributors of veterinary products. In practice, vets and para-vets are in the business of selling vet medicines. Drug shops managed by animal health technicians sell drugs in the rural areas. This is, however, not supported by the Pharmacy, Medicines and Poisons Act. The ECF vaccine is currently distributed by two private companies.	There are only two veterinarians in the private sector. AU-CTTBD is developing an ECF vaccine, which will be commercialized for distribution by partners, including the private sector.
Sale of registered pesticides.	Registered veterinary surgeons and veterinary para-professionals. Premises for storage and sale of pesticides are inspected and licenses issued under the Pest Control Products Act.	Pest Control Products Act. It is an offense to sell pesticides that are not registered.	The sale of pesticides for tick control is not well controlled. Veterinary assistants sell pesticides through drug shops in rural areas.	



Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Treatment (medicines)	Registered veterinary surgeons and veterinary para-professionals. Animal owners can treat their animals.	Control of Animal Diseases Act. Veterinary and Para-Veterinary Practitioners Act .	Veterinarians (very few), veterinary assistants and CAHWs offer treatments. They buy the drugs from drug shops that are also managed by veterinary assistants. Animal owners freely access all medicines and treat their animals or get para-professionals to do it.	The regulation of animal health service delivery is very weak – the Veterinary Board is not functional and the few veterinarians in the department cannot effectively cover the entire country to regulate animal health service delivery.
Vaccinations.	Registered pharmacists and manufacturers are licensed to sell veterinary vaccines. The Director of Veterinary Services decides which vaccines are to be used in animals. Veterinarians should issue prescriptions for the purchase of vaccines.	Pharmacy, Medicines and Poisons Act. Control of Animal Diseases Act.	The DVS maintains a record of authorized vaccines. Veterinarians (very few), animal health technicians and CAHWs offer vaccinations. Animal owners can buy nearly all vaccines from legal or illegal outlets.	Livestock production and disease control is not high priority in a country that is predominantly in subsistence farming. Demand for the ECF vaccine is waning.
Diagnostics – field kits.	Veterinarians or registered pharmacists can import diagnostic kits.	Pharmacy, Medicines and Poisons Act. The kits must be registered by the Pharmacy Board.	Field diagnostic kits are available within the veterinary services and in the private sector without registration.	Field diagnostics kits are not in use in Malawi.





4.5 Ethiopia

The regulation of the delivery of livestock health products and services in Ethiopia is done through proclamations from the Minister responsible for livestock. The role of the actors in the delivery of livestock health products and services is summarized in Table 5.

4.5.1 **Disease control**

Disease control is under the responsibility of devolved regional authorities. There are eight regional authorities that are responsible for the procurement of livestock health products through annual tenders. The regional authorities distribute the drugs through districts to village councils and veterinarians, animal health technicians and CAHWs offer diagnosis, treatments and vaccinations. Most of the vaccines are manufactured locally and are sold to farmers at low prices (Government subsidy). The National Vaccine Institute is a public enterprise that produces 17 different vaccines for trans-boundary animal diseases (public good) and other endemic diseases (private good) for local and export markets. The Institute is also involved in research and development, diagnostics, training of laboratory technologists and feed analysis. The Government pays for TAD vaccines and their distribution to the regions, whilst the cost of other vaccines is met by the farmers. The Government controls the price of locally-manufactured vaccines, and the last price review was in 1991.

4.5.2 Registration and sale of livestock health products

The regulation of the importation and registration of veterinary drugs has been under the Federal Drug Administration and Control Agency (DACA) within the Ministry of Health. It is intended that the newly-established Veterinary Drug and Animal Feed Administration and Control Authority within the Ministry of Livestock will be responsible for the registration and analysis of livestock health products and monitoring of residues. This institution is, however, in its infancy and is not functional. The distribution of veterinary drugs is privatized; wholesalers deliver to the regions through a tendering system. The Department of Veterinary Services under the Ministry of Agriculture at the Federal level has a co-coordinating role in disease control and veterinary policy. It, however, has no role in the importation of veterinary drugs – this is done by regional authorities through annual tenders to the private sector.

4.5.3 Registration of animal health service providers

Ethiopia currently has no statutory body for the registration of animal health service providers. It was not clear from the study if individuals or institutions in animal health service delivery need any registration.





Table five: FRAMEWORK FOR DELIVERY OF LIVESTOCK HEALTH PRODUCTS AND SERVICES IN ETHIOPIA

Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Registration of medicines, vaccines and diagnostic kits.	Registered pharmacists and manufacturers.	Drug Administration and Control Authority (DACA) of Ethiopia (under the Ministry of Health). Proclamation No.728 2011 establishes the Veterinary Drug and Feed Administration and Control to register and regulate veterinary drugs, vaccines and feed. Registration certificate is valid for a renewable five years.	The new authority has not started its operations in analysis and registration of livestock health products.	Post-registration and post-tendering surveillance is weak and many fake products are introduced, either after the registration of high quality products or after the award of tenders.
Importation of veterinary medicines, vaccines and diagnostic kits.	Registered pharmacists and licensed companies.	Drug Administration and Control Authority (DACA) of Ethiopia (under the Ministry of Health). Guidelines for the registration of veterinary drugs are available.	The importation of veterinary pharmaceuticals is liberalized. There is a thriving unofficial cross-border trade in unlicensed veterinary drugs.	
Distribution and sale of veterinary medicines, vaccines and diagnostic kits.	Companies with veterinarians. Cold chain is required for vaccines. Only vets can give prescriptions. Veterinarians and para-vets can sell and distribute vaccines and medicines.	Legal document not available	Veterinary pharmaceuticals are purchased through a tendering system managed by the regional governments. Generics and fake products have flooded some of the regions. The distribution network is poorly developed and the participation of private actors is very low.	Inspectorate services are weak – there is no veterinary board. The DVS has no control over the livestock health products being used in the regions.
Treatment (medicines).	Registered veterinary surgeons, para-vets, animal owners.	Legal document not available	Veterinarians, animal health technicians and CAHWs offer treatments.	It was not possible to ascertain the legal recognition of CAHWs, as there were no available documents and there is no veterinary board. Discussion with the Ethiopia Veterinary Association revealed that CAHWs have an important role in service delivery in the vast pastoral areas.

The legal documents from Ethiopia were not available. Most of the information on the legal position were obtained from key informants and validated at a policy workshop held in Nairobi in June 2014.



Livestock health products and services	Actors with legal recognition	Legal provision	Practice in place	Remarks
Vaccinations	The Director of Veterinary Services decides which vaccines are to be used in animals. Veterinarians, animal health technicians and animal owners.	Legal document not available	Most of the vaccines in use are locally manufactured by NVI and distributed at controlled prices (prices last reviewed in 1993). Veterinarians, animal health technicians, CAHWs and animal owners vaccinate animals in the field.	The Government does not provide adequate monitoring of vaccine usage and its impact on disease control.
Diagnostics – field kits.	Vets and para-vets. There are nine regional veterinary laboratories providing diagnostic services.	Legal document not available	Field diagnostic kits are available within the veterinary services and in the private sector without registration.	The regional laboratories are poorly linked to Federal Veterinary Services.

The legal documents from Ethiopia were not available. Most of the information on the legal position was obtained from key informants and validated at a policy workshop held in Nairobi in June 2014.





5 Conclusion

The Animal Diseases Act requires that owners of livestock must report an outbreak of any notifiable disease to the nearest veterinarian or veterinary para-professional (which includes animal health technicians). The veterinarian or para-professional investigates the outbreak, collects samples to ascertain the nature of the disease and applies control measures to minimize spread of the disease. Field diagnostic kits are not in use in any of the countries in the study. However, only registered veterinarians can use such diagnostic kits.

Veterinary boards (or councils) play an important role in regulating animal health service delivery. They define the training and qualification of animal health service providers and register qualified persons as veterinary surgeons, veterinary para-professionals (as happens in Kenya) or register veterinarians, enroll para-professionals and enlist para-professional assistants (as is the case in Tanzania). The veterinary boards determine the treatments that can be offered by para-professionals under the supervision of registered veterinarians. The boards in Uganda and Malawi are not effective in regulating animal health service delivery. Ethiopia is in the early stages of establishing a veterinary board.

Livestock NGOs operate in Uganda, Tanzania, Malawi and Kenya. There is evidence that some livestock NGOs want to venture into Ethiopia. The policy environment for livestock NGOs is conducive in these countries, but not in Ethiopia, where experience is limited. The VSVPP Act in Kenya gives powers to the KVB to register and license qualified individuals and NGOs to offer animal health services. NGOs offering animal health services must be registered and licensed by the Board and must employ a veterinarian to be in charge of animal health and welfare. In the other countries, it is not clear how NGOs and other institutions are registered and licensed to offer animal health services.

It is an offence to sell drugs, vaccines or diagnostic kits that are not registered by the competent authority (Pharmacy Boards or their equivalent). Only registered pharmacists can be licensed to distribute and retail veterinary drugs, vaccines and diagnostic kits, in registered and licensed premises.

Drugs that are listed as Part I poisons (which includes antibiotics and vaccines) can be sold to any person on presentation of a prescription from a veterinary surgeon. However, this is not strictly followed and drugs are often sold without any prescription.

Veterinarians can only stock limited amounts of drugs for use in the treatment of animals. However, in rural areas, veterinary drugs can be bought from drug shops that are not supervised by registered pharmacists.

In many of the countries, the legal framework does not recognize CAHWs as having any role in animal health service delivery. However, in remote areas it is clear that CAHWs are offering treatments and vaccinations. In Uganda, the CAHWs have a legal recognition to offer treatments and vaccinations in the pastoral areas, under the supervision of District Veterinary Officers. In such cases, NGOs train CAHWs in basic animal health for three months and facilitate them to buy drugs for animal treatments.

Private veterinary practice in Ethiopia, Malawi, Uganda and Tanzania is weak and only confined to urban and peri-urban areas. Private practice is strong in Kenya and the Kenya Livestock Finance Trust (KLIFT) avails commercial credit and business development services to support private practice in clinical services, the sale of livestock health products, farming and value addition; the KLIFT has supported very many livestock farmers and veterinarians, including 49 agro-vet shops managed by veterinary para-professionals.

The legal framework in all the countries allows farmers to treat their animals. From the information obtained, it can be inferred that in all the countries, farmers can access and buy a wide variety of livestock health products, including antibiotics and vaccines, and either administer the drugs themselves or get help from trained animal health service providers.



General Recommendations

- The registration and regulation of livestock health products in the five countries is not efficient or effective. There is a need to have autonomous veterinary medicine regulatory agencies, with an effective inspectorate to ensure only registered products are sold in the market. Ethiopia has established such an agency within the Ministry of Livestock. In Kenya, the VSVPP Act of 2011 has a provision for the establishment of a veterinary medicines directorate and an inspectorate.
- There is a need for Ethiopia to establish a Veterinary Board to regulate the delivery of livestock health products and services.
- Uganda has recognized that there are areas in the country that are not served by veterinarians and has authorized the use of CAHWs in treatments and vaccinations. In practice, all the other countries use CAHWs in pastoral areas, even though the law does not recognize them. It would be useful for these other countries to give legal recognition to CAHWs to provide limited animal health services in remote areas.
- There is a need to increase the level of awareness amongst livestock owners of the need to use drugs that are registered by competent authorities, in order to reduce the incidence of the use of low-quality, cheap drugs that do not offer effective treatments.
- The legal frameworks in Malawi and Uganda are very old and are in need of revision to define the qualifications and roles of the various actors (both individuals and institutions) in animal health service delivery. Tanzania and Kenya have very comprehensive and recent legislations in their Animal Disease Control and Veterinary Surgeons Acts.



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ANNEX 1: Terms of reference

POLICY LANDSCAPING OF LIVESTOCK HEALTH PRODUCT AND SERVICE DELIVERY IN EAST AND SOUTHERN AFRICA

BACKGROUND

GALVmed is a livestock health product development and adoption partnership focusing on sustainable poverty alleviation by making available and accessible animal health products (vaccines, medicines and diagnostics) to livestock keepers in the developing world who rely on livestock for their livelihoods.

GALVmed's purpose of 'Protecting Livestock Improving Human Life' is currently implemented in numerous countries in sub-Saharan Africa and in South Asia. GALVmed supports work on thirteen animal diseases across five species. GALVmed facilitates the adoption of livestock health products through appropriate and targeted interventions across the entire value chain, particularly focusing on where there are gaps or weak links. These sometimes occur at the marketing and distribution stage. GALVmed achieves its aims by working through partners, e.g. the private sector, governments, international organisations, universities, NGOs, community animal Health workers (CAHWs), self-help groups (SHGs), community service organisations (CSOs) and other actors.

Characteristically, GALVmed's work at the marketing and distribution stages often involves:

- Working with partners to deliver products in rural and remote/marginalised areas. These areas are often underserviced by public sector delivery of animal health services and by private veterinary professionals.
- Developing bespoke product delivery systems for ensuring sustainability. This often requires working with available actors and/or creating or facilitating incentives to encourage entrepreneurship in potential partners. This is a marked departure from conventional models that often comprise public sector/government campaigns to distribute products or use NGOs, with no sustainability built into the models.

There is anecdotal evidence that models using paraprofessionals, including CAHW and vaccinators, can be effective if supportive institutional and legislative frameworks exist. Whilst some countries where GALVmed operates have this supportive structure, most do not.

OBJECTIVES

GALVmed seeks to understand the policy constraints and opportunities to using actors outside the public sector/government mechanism in the delivery of livestock health products and services. These include private sector veterinarians, para-vets and paraprofessionals, NGOs, community animal health workers

(CAHWs), self-help groups (SHGs)/membership organisations and community service organisations (CSOs). GALVmed seeks to commission a policy landscaping study that will inform GALVmed's market development, adoption and global access strategies. The study will consist of an in-depth review of the policy, regulatory and administrative framework under which actors involved in the delivery of livestock health products and services operate in the specified countries. The study is expected to be explicit on the policy and practice.

For the purpose of this assignment, livestock health products are defined as vaccines, medicines and field (point-of-care) diagnostics. Livestock health services are defined as those relating to prescribing, selling, distributing and administering livestock health products.

PROJECT AREA

The policy landscaping study will cover these countries in east and southern Africa: Tanzania, Kenya, Uganda, Malawi and Ethiopia.

PROJECT DURATION

The appointment shall be for a period of two months effective from 1st August 2013 until 30th September 2013.

TASKS TO BE COMPLETED

The tasks will involve three distinct but related work activities:

Work Activity 1: Desk study and literature review

- 1.1 Conduct a desk study & literature review of the policies relevant to the framework of livestock health product and service delivery, with a focus on livestock vaccines, medicines and point-of-care/field diagnostics, clearly identifying constraints for organisations (NGOs, CSO, etc.) and for individuals (CAHW, vaccinators, etc.) in all the countries listed in Section 3 above. This would include looking at work done by other organisations/initiatives both regionally and at international level, including the OIE's PVS, AU-IBAR's Vet-GOV program, etc., and national legislation governing veterinary matters.
- **1.2** Identify information gaps to be supplemented by further data collection under Work Activity 2 below.

Work Activity 2: Designing questionnaires and administering them

- **2.1** Design data/information collection tools, i.e., questionnaires, in consultation with GALVmed.
- **2.2** Identify appropriate target respondents, including specific individuals representing various target institutions/actors/organisations, and share this list with GALVmed prior to making contact.
- **2.3** Contact identified respondents to gain access and arrange for field study and interviews.



Work Activity 3: Report writing

- **3.1** Prepare a draft report analysing the findings from Work Activities 1 & 2 and share the results and findings with GALVmed.
- **3.2** Prepare and present a final report, including recommendations.

METHODOLOGY

Work Activity 1 shall involve an in-depth analysis of primary and secondary sources. The primary sources are expected to include the national policies, strategies, Acts of Parliament and subsidiary legislation, including Ministerial Decrees, related to the delivery of livestock health products and services. Secondary sources are expected to include a literature review of national, regional and international reports and relevant studies. The consultant will be expected to consult and reflect international initiatives, debates and trends, particularly those under the auspices of e.g. the OIE, AU-IBAR and other relevant organisations where appropriate. The consultant will design questionnaires for qualitative data collection in consultation with GALVmed and will develop a list of appropriate respondents to whom questionnaires shall be sent, or who shall be interviewed during the fieldwork.

To supplement the information acquired in Work Activity 1, Work Activity 2 shall involve administering questionnaires and holding semi-structured qualitative interviews with the identified respondents. In each country, the respondents shall include representatives drawn from (i) the Government veterinary service, e.g. DVSs, veterinary councils, etc.; (ii) the private sector, including veterinary associations; (iii) public and private veterinarians; (iv) actors such as para-vets and para-professionals, NGOs, community animal health workers (CAHWs), self-help groups (SHGs)/membership organisations and community service organisations (CSOs); (v) vaccine, medicines and diagnostics stockists/retailers/distributors; and (vi) farmers. The final report shall include an Annex detailing the respondents and their contact details.

The report presenting the detailed review and findings from the Work Activities shall include:

- i. The stated legal/official position on the delivery of livestock health products and services in the stated countries, highlighting the differences and similarities across countries and regions where applicable.
- ii. The interpretation of the legal/official position (including evidence of that interpretation) by (a) the public sector, i.e., Government officials and public veterinarians; (b) the private sector; (c) other actors such as para-professionals, NGOs, CAHWs, SHGs and CSOs; (d) farmers.

- iii. The implementation of the various interpretations, i.e., the actual practice highlighting the differences and similarities across countries and regions where appropriate.
- iv. An exposition of actions regulated by professional bodies such as veterinary associations, rather than under the direct jurisdiction of stipulated country policies.
- **v.** A thorough analysis, particularly of the differences between policy and practice and the reasons for those differences where they exist.
- **vi.** The implications for and recommendations to GALVmed.

All the above points should consider: a) vaccination; b) medication; c) field (point-of-care) diagnostics.

All the above points, should consider: a) organizations; and b) individuals.

The reports shall be organised by country.

In addition, and not exhaustively, the study is expected to increase GALVmed's understanding of:

- The legal framework or delivery of livestock health products and services: What actors have legal recognition? How does the framework operate in practice? What sanction and enforcement measures exist?
- The characterisation of approved activities:
 What actors are allowed to do what and under what conditions/circumstances? e.g.:
 - > Vaccines: Who is allowed to vaccinate animals? How is vaccination defined? Are there different criteria based on, for example, disease, species, type of vaccine, etc.? What are these criteria? Who can prescribe, sell and/or distribute vaccines? What criteria/requirements must they meet, for example, concerning permits, storage facilities, etc.?
 - > Medicines: Who is allowed to medicate animals? Are there different criteria based on disease, species, type of medicine, etc.? What are these criteria? Who can prescribe, sell and/or distribute medicines? What criteria/requirements must they meet concerning permits, storage facilities, etc.?
 - > Field diagnostics: Who is allowed to use field diagnostic kits? Are there different criteria based on disease, species, type of field diagnostic? What are these criteria? Who can prescribe, sell and/or distribute these? What criteria/ requirements must they meet concerning permits, storage facilities, etc.?
 - > Further, what are the levels of vaccine, medicine and field diagnostics classifications?



- > Who is allowed to provide clinical diagnosis? Extension & training? Awareness and sensitization? What conditions/criteria are they required to fulfil?
- The livestock product and service delivery models/structures that may be in place: are there instances where governments contract agents to deliver certain services or products? Evidence of what structures works well and under what circumstances.

Findings should be explicit and distinguish between requirements for a) organizations and b) individuals, where this is relevant.

OUTPUTS/DELIVERABLES

The following are the expected outputs/deliverables:

- 1 Lists of relevant legislation and electronic copies where possible.
- 2 A list of potential interviewees/respondents, prior to commencing Work Activity 2.
- 3 A questionnaire to administer to respondents.
- 4 A draft report, comprising an analytical comprehensive review of the policy, regulatory and administrative framework.
- 5 A final report, including a brief presentation of the key findings.





ANNEX 2: Questionnaire for farmers

and ((2) south-eastern Africa
Coun	ntry
Regio	on
west of an	project is a Policy Landscaping of livestock health products and service delivery in central and sern Africa in (1) Eastern and Southern Africa and (2) Central and Western Africa. The study consists "in-depth review of the policy, regulatory and administrative framework under which actors involved a delivery of livestock health products and services operate in the specified countries".
your	nave been carefully selected as a valuable role-player in your country/region and we kindly request assistance in providing information concerning the delivery of livestock health products and services ur country/region.
Live	estock producer/keeper questionnaire
1	The farm
1.1.	FARMER CATEGORY Type of farming activity
1 Suk	bsistence farmer
1.2.	NUMBER AND TYPE(S) OF LIVESTOCK KEPT

Policy Landscaping of livestock health products and service delivery in (1) central and western Africa

Type of animal	Number
1 Cattle	
2 Goats	
3 Sheep	
4 Pigs	
5 Poultry (chickens, turkeys, geese, ducks etc)	
6 Camels	
7 Donkey/Mule	
8 Other animals, specify	

Number of livestock owned by Household/farm



1.3 ANIMAL HEALTH PRODUCTS AND SERVICE DELIVERY/USE

a. Do you use any medication/remedies to treat sick animals?

	1 Yes 2 No								
b.	If yes (to question 1.3a), what do you use to treat your animals?								
	1 Pharmaceuticals 2 Traditional remedies 3 None								
C.	If no (to question 1.3 a), who renders the service?								
	(1) Who provides the product to you?								
	(2) Please specify:								
	If none (to question 1.3b) why?								
d.	How do you grade the available livestock medication in your area?								
	(i) Quality of medication								
	1 Poor 2 Satisfactory 3 Good 4 Very good								
	(ii) Availability of medication								
	1 Poor Satisfactory Good Very good Satisfactory Satisfact								
	(iii) Affordability of medication								
	1 Cheap 2 Reasonable 3 Expensive 4 Too expensive								
e.	Do you vaccinate your animals?								
	1 Yes 2 No								
	(i) If yes (to question 1.3e), what do you use to vaccinate your animals?								
	1 Pharmaceuticals 2 Traditional remedies/methods 3 None								
	(ii) where do vaccines come from?								
	(iii) If so, for what diseases?								
	(iv) Who does the actual vaccinations (do farmers vaccinate themselves)?								
	(v) If not, who does it for them?								
	Same questions for medicines and diagnostics:								
	If none (to question 1.3e) why?								
f.	How do you grade the available livestock vaccines in your area?								
	(i) Quality of vaccines								
	1 Poor 2 Satisfactory 3 Good 4 Very good								
	(ii) Availability of vaccines								
	1 Poor 2 Satisfactory 3 Good 4 Very good								
	(iii) Affordability of vaccines								
	1 Cheap 2 Reasonable 3 Expensive 4 Too expensive								



g.	Do you use any livestock health services (e.g. vaccinators, animal clinics etc)?					
	1 Yes 2 No 2					
h.	If yes, please indicate, which services you frequently use:					
i.	If no, why					
j.	Who is the major provider of these services in your area?					
	1 Government / public 2 Private sector or NGO/CAHW					
	3 Both government and private organizations or GOV/NGO 4 None					
k.	Who is your preferred animal health services provider?					
	1 Government / public 2 Private sector or NGO/CAHW					
	3 Both government and private organizations or GOV/NGO 4 None					
l.	If none why?					
m.	How do you grade the available livestock health services (medicines, vaccines, diagnostics) provided in your area?					
	(i) Quality of livestock health services					
	1 Poor 2 Satisfactory 3 Good 4 Very good					
	(ii) Availability of livestock health services					
	1 Poor 2 Satisfactory 3 Good 4 Very good					
	(iii) Affordability of livestock health services (medicines/vaccine/diagnostics)					
	1 Cheap 2 Reasonable 3 Expensive 4 Too expensive					
	(iv) Accessibility of livestock health services					
	1 Poor 2 Satisfactory 3 Good 4 Very good					



ANNEX 3: Questionnaire for service providers

	(2) south-eastern Africa
Cou	ntry
Reg	ion
wes of a	project is a Policy Landscaping of livestock health products and service delivery in central and tern Africa in (1) Eastern and Southern Africa and (2) Central and Western Africa. The study consists in "in-depth review of the policy, regulatory and administrative framework under which actors involve the delivery of livestock health products and services operate in the specified countries".
your	have been carefully selected as a valuable role-player in your country/region and we kindly request assistance in providing information concerning the delivery of livestock health products and services our country.
Liv	estock health product and service provider questionnaire
1	Part one: General information
	a. What is your role in the livestock sector?
	1 Dealer in livestock medicines 2 Dealer in livestock vaccines
	3 Dealer in livestock diagnostics
	4 Dealer in all livestock services (medicines, vaccines and diagnostics)
	5 Provider of livestock health services
	6 Field diagnostics (including field diagnostic tool kits)
	b. Provide a brief description of your role in (a) above for example; producer/distributor of medicines to CAHWs or veterinary practitioner in region
	c. Which sector do you operate in? 1 Government/public sector 2 Private sector (e.g. individual, companies, NGOs) 3 Government/private partnership PRIVATE/NGO



created by	rovide your experience regarding the OPPORTUNITIES, CHALLENGES and/or HINDI government policies and regulations governing your operations (List policy/legislation) fow-up with opportunity, challenge and/or hindrance experienced).
	nt on the level of government enforcement regarding the above policies and briefly entering of accreditation of vaccine importers is poor because
•	re to suggest improvements in government policy and regulations governing your what would they be? (List policy first then your proposed areas of improvement.)
a. Kindly p created by and then fol can vaccina	Dealers in livestock medicines and vaccines ovide your experience regarding the OPPORTUNITIES, CHALLENGES and/or HINDI government policies and regulations governing your operations (List policy/legislation) ow-up with opportunity, challenge and/or hindrance experienced: Key point here is: who e? Medicate? Use diagnostics? What are the prerequisites they need in order to do this? iferent rules for organisations and for individuals and what are they?).
a. Kindly p created by and then fol can vaccina Are there di	ovide your experience regarding the OPPORTUNITIES, CHALLENGES and/or HINDI government policies and regulations governing your operations (List policy/legislation) low-up with opportunity, challenge and/or hindrance experienced: Key point here is: who



ANNEX 4: Key respondents interviewed

ETHIOPIA

Dr Getachew Jember Bizuney

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Dr. Karim Tounkara

Director
Pan-African Veterinary Vaccine Centre
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Dr. Wondwosen Asfaw

President Ethiopian Veterinary Association P.O.Box 2462, Addis Ababa, Ethiopia

Dr Bewket Siraw Adgeh

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Dr Martha Yami

General Manager National Veterinary Institute Debere Zeit Ethiopia

KENYA

Dr. Peter Maina Ithondeka

Director of Veterinary Services Ministry of Livestock Development Kangemi

Dr J. Jalang'o

Deputy Director of Veterinary Services Department of Veterinary Services

Dr. B. Odhiambo Godia

Executive Officer Kenya Veterinary Board Veterinary Research Laboratories, Kabete, Nairobi

Simplice Noula

AU-IBAR Chief Animal Production Officer Kenindia Business Park Museum Hill, Westlands Road P.O. Box 30786–00100, Nairobi

Dr Steve N. Kiniiya

Chief Executive Officer Kenya Livestock Finance Trust Nairobi

Dr Gathumbi

Bora Biotech Ltd – (Diagnostics) Cooper Centre, Kabete Nairobi, Kenya

Gabriel Turasha

Vetaid

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Mrs Charity W. Njoroge

Peri-urban livestock farmer Mirema Drive Kasarani

Dr Geoffrey Mutai

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Dr Jane Wachira

Deputy Director Kenya Veterinary Vaccines Production Institute

Dr Samuel Makumi

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Dr Ouko Elizabeth Omolo

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Dr Roggers Mosha

Project Manager – ND Africa GAI Vmed

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UGANDA

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Dr Ojala Robert

Chief Executive Officer Uganda Veterinary Association Plot 76 Buganda Road P.O. Box 16540, Kampala, Uganda

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ANNEX 5: List of legislations for delivery of livestock health products and services

Country	Delivery of livestock health services	Regulation of livestock health products	Remarks
KENYA	Animal Diseases Act – CAP 364 (Act No. 4 of 1965)		Gives powers to Director of Veterinary Services to authorize importation and use of livestock health products.
	Cattle Cleansing Act – CAP 358		Control of ticks and tick-borne diseases.
	Crop Production and Livestock Act – CAP 321		Very old legislation in need of revision.
	Pest Control Products Act – CAP 346 (Act No. 4 of 1982)		Licenses agro-vets to sell pesticides for control of ticks.
	The Veterinary Surgeons and Veterinary Para-Professional Act, 2011.		Defines what qualified staff and unqualified persons can or cannot do in animal health service delivery.
	Ministry of Livestock Development Session Paper No. 2 of 2008 on National Livestock Policy (Nov. 2008)		There is a need for a new livestock policy that embraces devolution of service delivery.
		The Pharmacy and Poisons Act – CAP 244 (R. 2009)	The law is repressive to veterinary surgeons and there is a move to set up a veterinary medicines directorate for the regulation of veterinary pharmaceuticals.
MALAWI	Control and Diseases of Animals Act – CAP 66.02		Very old legislation in need of revision.
	Regulation of the Veterinary Profession – 2001		
	Pesticides – CAP 35.03		
	Policy Document on Livestock in Malawi – 2006		
		Pharmacy, Medicines and Poisons Act – CAP 35.01	The law is repressive to veterinary surgeons, who are not allowed to distribute veterinary pharmaceuticals in the absence of a registered pharmacist.



Country	Delivery of livestock health services	Regulatory of livestock health products	Remarks
TANZANIA	The Animal Diseases Act No. 17 of 2003		
	The Veterinary Act, 2003		Caters for veterinary surgeons, para-professionals and assistant para-professionals.
	National Livestock Policy – Dec 2006		
		The Tanzania Food, Drugs and Cosmetics Act, 2003	The law is repressive to veterinary surgeons, who are not allowed to distribute veterinary pharmaceuticals in the absence of a registered pharmacist.
		TFDA guidelines for application for registration of biologicals – April 2004	
		TFDA list of registered products – veterinary pharmaceuticals	
UGANDA	The Animal Diseases Act – CAP 38		Very old legislation in need of revision.
	The Veterinary Surgeons Act – CAP 277		Very old legislation in need of revision.
	National Agriculture Advisory Services (NAADS)		
		National Drug Policy and Authority Act – CAP 206 of 1993	The law is repressive to veterinary surgeons, who are not allowed to distribute veterinary pharmaceuticals in the absence of a registered pharmacist.
		Guidelines on registration of vaccines and other immunological products for veterinary use in Uganda – August 2001	
ETHIOPIA			No legal documents were available.



ANNEX 6: List of key stakeholders interviewed

	Categories of interviewees	Ethiopia	Kenya	Uganda	Tanzania	Malawi	Remarks
1	Government/ public sector – veterinary services/ public vets	√	√	√	√	√	Chief Veterinary Officers or Designates in all the countries were interviewed. In Uganda, Tanzania and Ethiopia, the veterinary services have a central component in charge of policy and regulations and a decentralized component, operating under local or regional government, in charge of service delivery.
							Staff at the College of Veterinary Medicine, Animal Resources and Biosecurity (COVAB) and AFRISA at Makerere University were interviewed. AFRISA is facilitating the importation, distribution and delivery of the ECF vaccine in Uganda.
2	Veterinary Boards/ Veterinary Councils	ND	√	√	√	√	Ethiopia is considering establishing a veterinary board. The Veterinary Boards in Malawi and Uganda are not operational; in Uganda, the Board has poor governance and cannot provide independent quality assurance of veterinary training institutions. Strong and effective Boards/Council are operational in Kenya and Tanzania.
	Veterinary Associations	√	٧	V	√	٧	Presidents and past Chairmen of Veterinary Associations in Ethiopia, Uganda, Kenya and Malawi were interviewed. In Tanzania, only members of the TVA were interviewed.
3	Private vets and para-vets (individuals)	√	√	√	√	√	Private veterinary practice is weak in Ethiopia, Malawi, Uganda and Tanzania and only confined to urban and peri-urban areas. Malawi has only three vets in private practice. Private practice is strong in Kenya and the Kenya Livestock Finance Trusts avails commercial credit and business development services to support private practice in clinical services, sale of livestock health products, farming and value addition. KLIFT has supported very many veterinarians and farmers and is currently supporting 49 agro-vets, managed by veterinary para-professionals.



	Categories of interviewees	Ethiopia	Kenya	Uganda	Tanzania	Malawi	Remarks
4	Non-governmental organizations (NGOs)	ND	√	√	ND	ND	Livestock NGOs operate in Uganda, Tanzania, Malawi and Kenya. There is evidence that some livestock NGOs want to venture into Ethiopia (i.e., SIDAI). Due to time constraints, only VSF-Belgium was interviewed in Uganda. In Kenya, our key NGO contact failed to respond to our questionnaire following telephone interviews. The policy environment for livestock NGOs is conducive in these countries, except in Ethiopia where experience is limited.
5	Livestock producers/ Farmers	ND	√	ND	ND	ND	Discussions with other classes of respondents led us to infer that, in all the countries, farmers can access and buy a wide variety of livestock health products, including antibiotics and vaccines, and either administer them or get help from trained animal health service providers. The legal framework allows farmers to treat their animals. The purchase of ethical drugs is legally based on prescriptions from veterinary surgeons, but this is not the practice
6	Distributors of livestock health products	√	√	√	√	√	Private veterinarians and animal health technicians involved in the retail of livestock health products were interviewed in all the countries. The legal framework for registration of livestock health products is slow. The selling of veterinary drugs requires that the business employs a registered pharmacist, or that the pharmacist is a co-owner. Pharmacovigilance is very weak and, in all the countries, there is a high prevalence of fake and ineffective livestock health products.
7	Vaccine manufacturers	ND	٧	ND	V	V	In Kenya, individuals (veterinarians and animal health technicians) and institutions (NGOs) can buy vaccines from local manufacturers



ANNEX 7: Services to be offered by a veterinary para-professional and unqualified persons

SECOND SCHEDULE (S.23 (2)

The Veterinary Surgeons and Veterinary Para-Professional Act, 2011

A. SERVICES

The following may be performed by a veterinary para-professional:

- 1. Implementation of parasite control programmes in animals;
- 2. Meat inspection and other duties under the relevant legislation, if authorized to do so by the Director of Veterinary Services;
- 3. Delegated duties pertaining to regulated animal diseases, including the various eradication schemes;
- 4. Extension services (including training and education) to farmers and community members;
- 5. The collection, capturing and evaluation of data and the compiling of reports, whilst assisting with epidemiological and research projects;
- 6. The collection of samples, including blood smears, impression smears, skin and wool scrapings and faecal samples (excluding the collection of samples by biopsy);
- 7. The examination and analysis of samples, including blood smears, skin and wool scrapings, urine analysis and faecal samples and elementary clinical chemistry;
- 8. Basic post-mortem examinations and the collection and submission of samples;
- 9. Artificial insemination, provided that the veterinary para-professional is registered as an inseminator with the Director of Veterinary Services;
- 10. Any other function that may be assigned pursuant to this Act.

B. Procedures

- 1. Closed castration of cattle under 6 (six) months of age;
- 2. Closed castration of sheep and goats under 3 (three) months of age;
- 3. Open castration of pigs up to thirty days of age;
- 4. Dehorning of immature cattle, sheep and goats under 4 (four) months of age;
- 5. Tail docking of sheep under two months of age by using the open method;
- 6. Hoof trimming;
- 7. Under the responsibility or direction of a veterinary surgeon:
 - i. Lancing of abscesses;
 - ii. Treatment of septic wounds; and
 - iii. Administration of injections and medicines.
- 8. Any other function that may be assigned pursuant to this Act.



C. Execution of services

Notwithstanding the provisions of Parts A and B of this Schedule, a veterinary para-professional may perform the services referred to in Part A only during the course of delegated responsibility:

- a. As an employee of the Government; or
- b. As an employee of a registered veterinary surgeon.

D. Services to be carried out by unqualified persons

- 1. The rendering of treatment in an emergency for the purpose of saving life or relieving pain, provided the case is handed over to a registered veterinary surgeon or para-professional for follow-up.
- 2. The performance of any of the following operations by an animal owner on his own animals:
 - a. Closed castration of ruminants before the age of six months;
 - b. Tail docking of a lamb before the age of six months;
 - c. Amputation of the dew claws of a newborn puppy;
 - d. Debudding of a calf under the age of four weeks.

Provided that, without prejudice to the foregoing paragraphs of this Part:

- (i) The operations specified in (a) to (d) of this paragraph shall only be performed by persons of the age of or above eighteen;
- (ii) Nothing in this Act shall authorise the castration of any animal mentioned hereunder after it has reached the age respectively shown:

Bullsix months.

Goatthree months.

Ramthree months.



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