

Veterinary Medicines Regulatory Alignment between Federal and Regional Regulatory Bodies of Ethiopia

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Abstract

Executive Summary: A semi-structured questionnaire based descriptive study was conducted from May to June 2018 in four regions of Ethiopia, including Oromia, Tigray, SNNP and Afar with the objective of assessing the regulatory alignment between federal and regional veterinary drugs regulatory bodies and identifying the major factors contributing to the fragmentation of regulatory functions between the agencies. Heads of the regulatory bodies, experts working within the regulatory bodies and private business actors were interviewed for the study purpose. A review of legislations was also done to assess the regulatory functions given to the regulatory bodies and their coincidence to each other.

Key Findings: Veterinary drug and animal feed administration and control proclamation 728/2011 is the core national governing legislation for the regulation of veterinary drugs and animal feeds. Following directive, Veterinary Drug Retail Outlets Certification and Control Directive 02/2015 is also issued by VDFACA to administer and control the retail outlets. The regulatory functions of trans-regional and trans-boundary production, import, export and distribution of veterinary drugs are given to the federal veterinary drugs and animal feed administration and control authority (VDFACA); while the regional regulatory bodies are given the responsibility of regulating trade and distribution activities conducted within the regional territories. But functions that could be done concurrently by both agencies and the system of harmonizing the regulatory activities are not covered in the legislations. The border line between feed and medicine is not covered on the legislations, leading to conflict of interest between feed and medicine regulators on the regulation of medicated feeds. The inspection procedures of how to inspect, what to inspect, how frequent to inspect, inspection approaches, and sampling techniques are not described in the directives. Even though, the proclamation gives the responsibility to issue a list of veterinary drugs that may be prescribed by veterinary professionals other than veterinarians and those which could be dispensed without prescription, it is not yet issued; which is affecting the good distribution and retail practice. Oromia regional state is the only region established an independent veterinary drug and feed regulatory body. In the rest three study regions (Tigray, SNNP and Afar) regulatory body is not established due to poor awareness of regional law making and higher executive bodies and shortage of budget; and the regulation is being done by delegation. Only one

expert is assigned to work on veterinary medicines regulation in Oromia region, but animal health experts are assigned to work as a secondary responsibility in the other regions. These all experts don't have a short or long term training certificate or academic background on regulatory affairs. So that, the study showed that they lack a skill to identify illegal drug related defects.

The federal VDFACA and regional regulatory bodies never planned together and shared report of their regulatory activities. They don't have also an official meeting schedule to discuss on common regulatory challenges and their possible solutions. There are no tools and an experience of reporting product related risks to each other. Horizontal integration and cooperation of regions is not also started yet; which leads to have the regulatory bodies different awareness and regulatory performance. Systems are not established to involve professionals, private sectors and the community in the regulation of veterinary medicines.

Conclusion and Recommendations: Legislative, structural, communication and regulatory tools related gaps are identified in this study; which are enervating the regulatory alignment between federal and regional regulatory bodies. Harmonization of legislations and regulatory tools, development of vertical and horizontal communication mechanisms, harmonization of regulatory plans and capacity development and awareness creation programs should be done to align the regulatory activities and ensure uniform regulatory awareness and performance.

Abbreviations: VDFACA: Veterinary Drugs and Animal Feed Administration and Control Authority; VMD: United Kingdom Veterinary Medicines Directorate; SNNP: Southern Nations Nationalities and People; SOP: Standard Operating Procedure; MNB: Multi-Nutrient Bloc; CSA: Central Statistics Agency; CDSCO: Drugs Standard Control Organization; SDRAs: State Drug Regulatory Authorities; HPR: House of Peoples Representative; BVSc: Bachelor Of Veterinary Science.

Introduction

Veterinary medicines are fundamental for treatment, prevention and control of both infectious and non-infectious animal diseases. Provision of successful animal health service requires the availability of safe, effective and of the required quality and quantity of veterinary drugs. In addition, the available drugs must be presented and used rationally. The use of ineffective, poor quality, harmful drugs can result in therapeutic failure, exacerbation of disease, resistance to drugs and sometimes death [1]. It also undermines confidence in animal health systems, animal health professionals, pharmaceutical manufacturers and distributors. Money spent on ineffective and poor quality drugs is wasted whether by consumers or governments [2]. Improper utilization of veterinary drugs is also a threat to public health since majority of drugs used in veterinary medicine are structurally and functionally related to human

therapeutics which may select for co-or-cross resistance [3] and adverse drug effects due to drug residues consumed with animal products.

The effective regulation of veterinary medicines requires a strong regulatory framework at all levels of regulation. The major elements of regulatory framework which contribute to the success of a regulatory bodies include adequate legislations and appropriate tools, such as standards, guidelines and procedures, appropriate organizational structure and facilities, clearly defined roles and responsibilities, sufficient qualified and experienced professionals, adequate and sustainable financial resources, effective cooperation between the regulatory bodies and other government institutions including those dealing with law enforcement (e.g. trade, customs and police), and transparency and accountability combined with good management [4,5].

In some countries, regulatory functions come under the jurisdiction of a single agency with full authority over the command and control of all regulatory activities. But in countries with a federal system of government, these functions are distributed between different authorities, either horizontally (e.g. ministry of health, ministry of agriculture) or vertically (federal, state and local governments) [6]. India is one among the countries with federal system of government, the medicines regulation functions distributed to the Central Drugs Standard

Control Organization (CDSCO), the national level regulator, and State Drug Regulatory Authorities (SDRAs). CDSCO is responsible for granting approvals for clinical trials, new drugs and specialized medicinal products (vaccines, parenterals, and other high risk products) and authorizations for import and export. SDRAs are responsible for granting manufacturing, distribution and sale licenses, inspections, sampling and testing and overall quality control of medicinal products (including investigating violations and launching prosecutions) [7].

In Ethiopia veterinary drugs were regulated together with human medicines under a single regulatory body, drug administration and control authority [8], until an independent veterinary drugs and animal feed regulating body was established after the promulgation of veterinary drugs and animal feed administration and control proclamation 728/2011 [9] by the parliament in 2011. Veterinary drugs and animal feed administration and control authority (VDFACA) of Ethiopia is established as per the council of ministers regulation 272/2012 [10] to execute the regulatory activities stated on the proclamation.

Ethiopia has a tiered governmental system consisting of a federal government and regional states. The country is divided into nine politically autonomous regional states and two city administrations (Addis Ababa and Dire Dawa cities). The regional states also oversee zones, woredas (districts) and kebeles. In countries with a federal system of government like Ethiopia, with the regulatory activities are vertically distributed to federal and regional governments, requires concerted effort between the agencies at all levels in order to attain the same regulatory objectives for the entire country. Such a system also requires coherence of regulatory objectives between the federal and regions, and considerable investment in resources for efficient delivery of regulatory functions.

Objectives of the Study

The study was designed to give us the following outputs, which they will help to develop effective regulatory strategies to enhance the good distribution of veterinary medicines.

- A map of the current regulatory landscape and legislations governing the establishment and roles of all the relevant federal and regional bodies.
- Legislative gaps in the regulation of veterinary medicines

- The major challenges causing fragmentation of regulatory functions between federal and regional agencies
- Availability and application of regulatory tools
- Communication gaps between the regulatory bodies
- Major regulatory skill and knowledge gaps
- Regulatory hurdles/challenges identified by stakeholders
- Recommendations for addressing the identified gaps and improving regulatory delivery

Scope

The study was conducted from May to July 2018 in four regions of Ethiopia, including Oromia, Tigray, SNNP and Afar. Selection of these regions is based on the judgment that they represent the different livestock production systems of the country. Tigray represents the mixed crop livestock farming system; Oromia and SNNP represent the crop livestock mixed farming and pastoral areas; and Afar region purely represents pastoral production system. These four regions also cover above 74% of the total area of the country [11]. According to the Ethiopian central statistics agency (CSA) report on livestock and livestock characteristics shows 70.2% of cattle, 65.94% sheep and goat, 64.6% equines, 68.6% camels and 63.1% poultry are found in these regions. Among the 1326 veterinary drug retail outlets found in the country 943 (71.1%) of them are found within these regions, with 108 in Tigray, 609 in Oromia, 214 in SNNP and 12 in Afar [12].

Study Methods

Data was collected by key informants' interview, including the managers or heads and experts of the regional regulatory bodies and the private business actors which are involved in distribution and retail of veterinary drugs. A total of 12 respondents from the regulatory bodies and 17 private business actors from all regions are involved in the study. The current regional regulatory structure and their knowledge and skill to regulate veterinary medicines were studied. Legislative review was also conducted to look on if the responsibilities and powers given to the regional and federal regulatory bodies are clearly defined and to assess if they coincide to each other. Regulatory communication and mechanism of reporting of activities between the agencies was assessed. The study also tried to identify the major gaps challenging the uniformity of regulatory command in the country.

Result

Legislation Review

The veterinary drugs and animal feed administration and control proclamation 728/2011 promulgated by the higher law making body, house of peoples representative (HPR), give the regulatory functions to federal and regional governments. Setting standards in relation to veterinary drugs, feed and veterinary drug professionals; and regulating trans-regional veterinary drug and feed production, distribution, promotion, storage and quality control and veterinary drugs and feed import and export activities are given to federal VDFACA. Whereas the regional states regulatory bodies are given the mandate to regulate veterinary drugs and feed circulating only within their administrative territory. But, the proclamation doesn't include any provision on regulatory functions to be done concurrently by both federal and regional bodies and how they could harmonize their activities.

Article 10 of the proclamation 728/2011 stated about good prescription and dispensing practices of veterinary drugs. Article 10 (1) provides that "veterinary drugs shall only be prescribed by a veterinarian". The veterinarian prescribing drugs is also required to follow prescription procedures and on standard prescription papers. Giving the mandate of prescribing practice to veterinarians only may affect the distribution and supply of veterinary medicines. A lot of animal health professionals such as bachelor of veterinary science (BVSc) are graduating from different universities which can also involve in the prescription practice but they are denied in the proclamation. Under article 10(3) veterinary drug shall only be dispensed by a veterinary drug professional (veterinarian or animal health assistant, or a pharmacist, druggist or pharmacy technician engaged in providing professional service in relation to veterinary drugs) holding professional license. Any veterinary drug professional shall dispense veterinary drugs with care by providing sufficient information and awareness based on dispensing procedures. Although, Article 10 (5) of the proclamation states that "the Authority may, by directive, issue the list of veterinary drugs that may be prescribed by veterinary professionals other than veterinarians and those which could be dispensed without prescription", the authority didn't develop the directive yet.

Proclamation 728 has some important provisions with regard to quality control. It prohibits sale of unlabeled, substandard counterfeited products. Under article 16 (1) any importer; or producer; or distributor of veterinary drugs; or veterinary pharmacy may not supply drugs to

the market or distribute or sale it unless duly packed and labelled. Furthermore, the inspector who is to be appointed by the Authority or by regional government body is given extensive powers and duties to regulate counterfeit or substandard products. The inspector has the power to order quarantine of veterinary drugs, feeds or feed additives suspected of being adulterated, spoiled, counterfeited, contaminated, or those suspected to be dangerous to users until such products undergo quality control test and the results are known. The inspector has also the power to enter, during working hours, any premise where veterinary drug or feed trade is carried out or veterinary drug or feed is stored; or stop any carrier loaded with veterinary drug or feed and undertake inspection. He/she may inspect documents, records, prescriptions, and computers related to veterinary drug and take copies of such documents as may be necessary. The inspector may also take samples of products; in accordance with the directives issued by the Authority.

According to article 3 of the proclamation, regulation of dispensing activity is given to regional regulatory bodies. VDFACA developed a model directive called "Veterinary drug retail outlets certification and control directive 02/2015" [13] and distributed to the regions for harmonized certification of retail outlets all over the country. Qualified veterinary drug professional, standard storage and dispensing premises and sanitation rooms (toilet and bath rooms) are the major requirements for an individual to get certificate of competence. According to Article 7(1&3) of the directive a veterinarian or veterinary pharmacies or BVSc is required as a technical manager for veterinary drug shop while animal health assistant or druggist or veterinary pharmacy technician or above is require for rural veterinary drug shop. Storage and dispensing rooms with clean and easily cleanable roof, wall and floor, well ventilated and lighting, and having all storage and dispensing materials as well as continuous water and electricity supply are the requirements stated on article 7 of the directive.

Article (8) of the directive states the procedures of issuing certificate of competence. First, the applicant should fill the application form and submit to the regulatory body. Then three inspectors from the regulatory body will inspect the premise. Based on the inspection and accompanying documents the regulatory body will decide on the issue of certificate of competence. If the regulatory body is not going to give the certificate to the applicant, it should notify him in written form sating the reasons and inspection deficiencies. The applicant can ask for re-inspection for consecutive two times. Article 6(2) of the directive states, the regional regulatory bodies

should conduct post-certification inspection to check if the retail outlets are working by maintaining the legal requirements. But nothing is describes how, what and how frequent the inspection should be conducted.

Gaps:

- The legislations don't have provisions on regulatory functions to be done concurrently by both federal and regional regulatory bodies and how could they harmonize their activities
- The mandate of prescribing veterinary medicines is given only to veterinarians, which is restricting other qualified professionals from the practice.
- A list of veterinary drugs that may be prescribed by veterinary professionals other than veterinarians and those which could be dispensed without prescription is not issued.
- The post-certification inspection procedure, including how to inspect, what to inspect, how frequent to inspect, inspection approaches, and sampling techniques, is not described in the directives.
- The border line between feed and medicine is not covered on the legislations, leading to conflict of interest between feed and medicine regulators on the regulation of medicated feeds.

Illegal Trade of Veterinary Drugs

All the respondents mentioned that there is illegal trade of veterinary drugs which is described by the involvement of individuals in veterinary drug business without getting license, illegal trafficking of drugs from neighbouring countries or regions, selling of veterinary drugs on open market and non-veterinary drug shops, and selling of antibiotics without prescription. These are caused by poor capacity of the regulatory bodies to enforce the laws, poor coordination of the law enforcing bodies (RA, trade, customs, police & judiciary), weak institutional alignment and coordination between regional and federal regulatory bodies and inter-regional connections, poor awareness of the stakeholders (political leaders, professionals and owners), weak involvement of the community in the regulatory activities, weak control at border areas, and low supply and demand ratio of medicines and poor regulation of veterinary service and animal health professionals.

Due to the availability of illegal trade of veterinary medicines the legally licensed private actors are facing a lot of challenges in their business. They claimed that they are losing their profits and are not able to compete with these illegal actors as illegal once are selling the products with less price because they are getting the products from

illegal source which is cheap, they don't have administrative cost and don't pay tax.

Veterinary Drugs Regulatory Structure and Alignment

Organizational Structure and Resources of the Regional Regulatory Bodies: Oromia region is the only region having an independent regulatory structure called regulatory directorate established under bureau of livestock and fishery resources. The structure is also down stretched to regional and woreda levels with one veterinary drug regulatory expert position set at each level. In the rest of regions the regulatory activities are being done by delegation. Animal health experts working under animal health and quarantine core process, animal health directorate and animal and plant health inspection and quarantine core process in Tigray, SNNP and Afar regions respectively are delegated to work the regulatory activities as their secondary job. It is only indicated in the job description of SNNP region experts. Although the experts and other individuals are continuously asking for the establishment of independent regulatory body, the higher officials and law making bodies are not responding either because of lack of awareness or because of budget constraint. Even though there are regulatory positions at the lower administrative levels (zone and woreda) of Oromia region, experts are not fully recruited because of shortage of budget.

All regions are using "veterinary drug retail outlets certification and control directive 02/2015" to certify and control retail outlets. But, the administrative level where the certificate of competence to veterinary drug distributors and retail outlets differs from region to region. In Oromia region certificate is issued at zone level following premises inspection reports and supportive documents sent from woredas. However, the regional body is responsible to certify institutions in SNNP and Afar regions. In SNNP region committee established at woreda level inspects the premises and check the professional qualifications and other documents and send the inspection report and all documents to zone and then after cross checking the reports and documents with legislative requirements send it again to region for certification. But in Afar region, regional experts directly go down to inspect the premises following individual's application and then issue certificate of competence. On the other hand, the woreda committee inspects and cross check documents and issue certificate of competence for retail outlets and the regional body inspects and issue certificate for wholesalers in Tigray region.

Government budget is the only source of finance for the regulation of veterinary medicines and feed in all regions. The higher officials also don't give priority to the regulatory sector so that they may not allocate budget for it. Tigray, SNNP and Afar regions don't have a specific budget allocated for the purpose of veterinary drug and feed regulation. Due to this the delegated regulatory experts don't have a specified regular or routine inspection program. They only try to go out of office on average twice a year to inspect few institutions by integrating with other sectors for common use of resources such as vehicles and fuel. None of them also have a risk based inspection strategy. Afar region never go back to inspect the institutions after they issued certificate of competence.

Regulatory Knowledge and Skill: The experts working as veterinary drug regulators are veterinarians (DVM), bachelor of veterinary science (BVSc) and animal health assistants by profession. All the experts at least participated in either of the awareness creation workshops on veterinary drug regulation or trainings on rational use of veterinary drugs organized by VDFACA. But, no one have official short or long term training certificate or academic background on regulatory affairs.

It is found that the regulatory experts lack skill to identify illegal veterinary drugs in the market. Experts in Oromia region mentioned a list of registered medicines as a reference to identify registered from non-registered drugs. Tigray and SNNP regions use list of registered drugs to check their registration and an invoices to ensure their legal source. Afar region responded that they don't know how and never tried to differentiate legal and illegal veterinary drugs in the market. They didn't mention the physicochemical methods of analysis as well as identification of labeling and packaging defects as a method of product quality control.

Regulatory Alignment and Involvement of Stakeholders in the Regulation: The regulatory functions of VDFACA and regional state regulatory bodies are based on the provisions of "veterinary drugs and animal feed administration and control proclamation 728/2011". Their different roles and responsibilities are indicated on article 3 and 20 of the proclamation. But the proclamation didn't indicate any regulatory activities and functions to be done concurrently by both federal and state governments. How they can coordinate and integrate each other is not also boldly provided in the proclamation or not supported by other directives. Only article 20(12) give the responsibility to VDFACA to give training for the appropriate organs in handling and

utilization of veterinary drugs and feed. Based on that, VDFACA is giving continuous trainings to regional animal health professionals since 2015. The regions also appreciated this despite it wasn't planned and organized together. The authority is sending some product related alerts to the regions but the Afar region experts didn't agree with this as they responded that they never received any alert from the authority. On the other side none of the regional regulators experienced reporting of product related safety, quality and efficacy problems to VDFACA. The regions also mentioned that VDFACA is helping them in community awareness development (commonly called "community mobilization") and legal literacy. But, these activities were planned and done by VDFACA alone without the involvement of the regional regulatory bodies.

All regional respondents mentioned as they don't have regular bilateral meetings and discussions with VDFACA. They also claimed that VDFACA isn't letting them to plan and act together. The agencies don't have a formal way of communication and report sharing mechanisms. For example, VDFACA don't continuously send an updated list of registered veterinary drugs and list of manufacturers, importers and wholesalers issued certificate of competence to Regional regulatory bodies. As it was seen during the study the lists were obsolete (un-updated). The regional regulatory bodies are not also regularly sending the list of distributors and retail outlets certified in their respective regions. Even the regions themselves don't have a formal way of communication between their administrative levels.

Horizontal communication and coordination of the regional regulatory bodies is also very poor. They only discuss common issues when they meet during VDFACA workshops and trainings. The work link and cooperation with other stakeholders such as trade and custom offices, police and judiciary bodies is not also strong and not supported by formal bilateral and multilateral discussions and memorandum of understanding. There is no established mechanism enabling the professionals and community to report illegal and/or defective products to the regional regulatory bodies. Only mass awareness creation programs are done in Oromia and SNNP regions.

Conclusion and Recommendations

Majority of the regions don't have independent veterinary drugs regulatory body and designated experts. The major problems in the regulatory system are lack of horizontal coordination between the regional regulatory bodies; and absence of a command chain between

regional and federal regulatory agencies that are happened because of poor communication between the regulatory bodies due to unavailability of communication tools and established mechanisms, poor harmonization of regulatory plans and tools at all levels, and poor integration of the regulatory bodies with other stakeholders. Lack of regulatory skills of the regional experts and poor awareness of all individuals and stakeholders having part in the regulatory activity are also the major gaps identified.

To strengthen the coordination and alignment of the regulation of veterinary medicines and animal feeds between both federal and regional regulatory bodies, the following recommendations are forwarded.

- A list of veterinary drugs that may be prescribed by veterinary professionals other than veterinarians and those which could be dispensed without prescription should be developed.
- The function of animal feed and feed ingredients regulation should be either shared to both federal and regional regulatory agencies or separately given based on the level of the business institutions.
- A border line between feed and medicines should be clearly identified and provided by legislation.
- Acceptable limit for aflatoxin in animal feeds should be developed
- All regulatory tools such as inspection manual and checklist should be harmonized and distributed to all regional regulatory bodies.
- VDFACA and all regional regulatory bodies should start planning and implementing together and share reports; this could help both agencies as a means of capacity building, effective use of resources and for common understanding and uniformity of regulatory performance.
- Capacity building training should be given to regional regulatory bodies to improve their regulatory knowledge and skills.
- Creating an information sharing and communication mechanisms between the regulatory bodies is also necessary.
- All regulatory bodies should have a multilateral regular meeting and discussion schedule to identify regulatory challenges and set possible solutions.
- Awareness creation programs should be organized to improve the awareness of regional law makers, higher executive bodies, professionals and other stakeholders.
- A mechanism should be developed to involve private sectors (distributors and retailers) and the community in the regulatory activities.

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