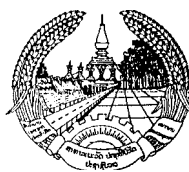


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Lao People's Democratic Republic
Peace Independence Democracy Unity Prosperity

Government

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Decree
On Veterinary Medicines

Chapter 1
The Categorization and Listing of Veterinary Medicines

Article 1 Objectives

This Decree determines principles, regulations and measures on the management, monitoring-inspecting of veterinary regime to conform business operation and the use of veterinary machines to technical principles to assure productivity, efficiency and life safety of people, animals and environment contributing to the national perseverance and development.

Article 2 Veterinary Medicines

Veterinary medicines are medicines preventing diseases, curing and supplementing health of animals and aquatic animals such as vaccines, anthelmintic, vitamins accurately registered with the Ministry of Agriculture and Forestry, which include processed foods medical, chemical substances or semi bio substance medicals, raw medical materials used in veterinary medicines

Article 3 Terminology

Terms used in this Decree mean the followings:

1. Antimicrobials means veterinary medicines extracted from any microbiomes and from chemical synthesis, which can activate or stop microbiomes from growing or separating and causing diseases in animals.
2. Antibiotic means any substances formed by microbiomes such as bacteria that could prevent or stop growth or with destroying stimuli on another group or other groups of microbiomes.
3. Antimicrobials resistance means the ability of bacteria or other fungi that could grow or survive when touching with antimicrobials with adequate intensity to prevent or proven treatment.
4. Ingredients of veterinary medicines are materials from natural extract or synthesis and are main medicines with preventing activation and direct treatment, supporting ingredient medicals stimulating the effective activation of main medicines and inactive medical ingredients to formulate medicines in different forms such as flavoring substances, taste, color or substances formulating medicines in different shapes such as water, liquid, bar, powder, capsule or tablet
5. Animal feeds containing veterinary medicines mean products derived from the mixture of animal feeds and veterinary medicines with the purpose to nurture, protect or specifically cure diseases in certain animal and aquatic animals

6. Veterinary medicine book means formulas used to produce medicines, which indicates ingredients and quantity of medicines that are mixed to produce finished products of veterinary medicines
7. Containers mean any material used to specifically store or package of veterinary medicines
8. Labels mean images of texts attached or printed on the container, which gives information on names of veterinary medicines, quality, benefits, ingredients, date of manufacture, expiration date, storage mode, usage and information of the manufacturers
9. Prescription means documents comprising information of the veterinary medicines attached on the product or in its container making readers understand meanings and detailed information of veterinary medicines
10. Permittees mean individuals, legal entity or organizations who are given a permit by the organization managing veterinary on their production business, import, sell, export or transit of the veterinary medicines
11. Counterfeit veterinary medicines mean the imitated veterinary medicines claiming they are genuine medicines with their trademarks or location of the producers are deceived or medicines that are not in accordance with their registration or medicines showing inaccurate label or prescription or the veterinary medicines mixed with counterfeit veterinary medicines or under the specified registration standard of the organization managing veterinary medicines.
12. Veterinary medicines that do not meet standard are the medicines with quantity or severity of the activation less than minimum or more than the maximum as specified in registered list of medical formula or are the medicines with ingredients and purity values and different characteristics as registered or be mixed with unregistered and vile standard veterinary medicines as required by laws.
13. Degraded veterinary medicines are expired medicines or be found later that the medicines have been transformed their characteristics similar to counterfeit medicines or do not satisfy standard or be mixed with degraded medicines;
14. Pharmacists are the people who graduate from medical school holding of at least a bachelor's degree.

Article 4 Government policies for veterinary

Government prioritizes the work of veterinary by training human resources, researching, testing, developing and transferring technical knowledge on veterinary which includes infrastructure building, technical materials to assure efficiency.

Government promotes and encourages individual, legal entity and organization to invest in business operation on veterinary, using local potentials on the natural resources to process medicines, which includes the promotion on production and veterinary medicines supply by supplying information, technical knowledge and tariff policies, tax in accordance with laws and regulations.

Article 5 Principles on the management of veterinary medicines

Managing veterinary medicines must follow these principles:

1. Conform to policies, laws, regulations, treaties and international treaties which Laos is a member of;
2. Centralize the management and unite across the country;
3. Assure quality, efficiency and safety on the health of animals, aquatic animals, consumers and environment;
4. Assure transparency, justice and able to inspect.

Article 6 Scope of Application

This decree is effective with individuals, legal entity or domestic and international organization that run business on veterinary medicines in Laos.

Article 7 International Cooperation

Government promotes oversea, regional and international cooperation on veterinary medicines through the exchange of lessons, information, scientific research, techniques-technology, human resource development, technical assistance and fund to meet productivity and efficiency.

Chapter 2 Categorization and listing of veterinary medicines

Article 8 Categorization of Veterinary Medicines

Veterinary medicines in Lao PDR are categorized in 4 types as following:

1. Veterinary medicines with prescription only;
2. Veterinary medicines sold and distributed by pharmacists without prescription;
3. Veterinary medicines sold and distributed by authorized dealers;
4. Veterinary medicines generally sold and distributed.

Veterinary medicines with prescription only are medicines in the controlled lists and limited use as specified in international rules, which determine to be sold and distributed by veterinarians or pharmacists with authorized prescription.

Veterinary medicines sold and distributed by pharmacists without prescription are medicines that need to introduce the risk of using or side effects on users and must be sold and distributed by veterinarians or pharmacists stationed at the medicines store or at authorized dealers prior to the sales or distribution with or without medical prescription.

Veterinary medicines sold and distributed by authorized dealers are certain groups of veterinary medicines sold and distributed by veterinarians, pharmacists, and dealers or authorized distributors, but cannot be grouped as general sales or distribution.

Veterinary medicines generally sold and distributed are medicines that can be sold and distributed by general individuals who are not veterinarians or pharmacists, but such sales are not allowed to unwrap the packages from manufacturers or be separated for sub-sales.

Article 9 List of Veterinary Medicines.

Ministry of Agriculture and Forestry collects and creates the necessary, very necessary, and the most necessary list of veterinary medicines to be used in livestock, veterinary and fisheries in accordance with groups of pharmacy and instructions of relevant international organization with having a proper review periodically and must prioritize veterinary medicines registered, produced, imported, distributed and sold.

Article 10 Possessions of Veterinary Medicines

Possession of veterinary medicines follows these cases:

1. Veterinarians at clinics, veterinary clinics, research center, farms, educational institute;
2. Authorized persons to run business on veterinary;
3. Owners of livestock or persons authorized by veterinarians to cure sick livestock or caretakers while transporting livestock.

Chapter 3 Registration of Veterinary Medicines

Article 11 Registrations of Veterinary Medicines

Prior to the production, import, export and sales, persons with authorization to run a business on veterinary medicines must register for veterinary certificates with the Department of Livestock and Fisheries, Ministry of Agriculture and Forestry.

Unregistered veterinary medicines before this Decree comes into effect, persons running businesses on veterinary medicines must register for a certificate of veterinary medicines with the Department of Livestock and Fisheries within 180 days from the day the Decree comes into effect.

Article 12 Veterinary Medicines with Exemption to Register

Veterinary medicines that are exempted for registration in Lao PDR are as following:

1. Samples of veterinary medicines used for study, analysis, analysis;
2. Veterinary medicines for exhibition;
3. Veterinary medicines that come with the owners of livestock or veterinarians who are with the transport of livestock;
4. Veterinary medicines exempted for the permission to run a production business, import or sales as specified by the Ministry of Agriculture and Forestry.

Veterinary medicines that receive exemption to register in Lao PDR must provide their cooperation to the organization managing veterinary medicines in case of inspection and monitoring take place.

Article 13 Veterinary Medicines without Permission to Register

Veterinary medicines that are not permitted to register are as following:

1. Their certificates are withdrawn in Lao PDR or in foreign countries;
2. Those include dangerous chemicals and other substances that are not safe to animals and users;
3. Those attach labels not in accordance with Lao culture or can deceive from the fact;
4. Those having impact on environment or illegal substance as regulated by the Ministry of Agriculture and Forestry.

Article 14 Registration Conditions for Veterinary Medicines Certificate.

Conditions to register for a certificate on veterinary medicines are as following:

1. Veterinary medicines that are produced, imported, exported or sold in Lao PDR;
2. Veterinary medicines that are use tested, quality researched and safe;
3. Veterinary medicines that are imported, registered from manufacturing country and received authorization from manufacturers of the exporting country;
4. Supply documents and samples of veterinary medicines as demanded by the Department of Livestock and Fisheries, Ministry of Agriculture and Forestry;
5. In case of repetitive registration must be agreed in a written form from a certificate holder.

Article 15 Documents and Samples of Veterinary Medicines

Documents and samples of veterinary medicines to register for a certificate are as following:

1. Supply a request letter as specified by the Department of Livestock and Fisheries;
2. Supply a Xeroxed copy of a business registration certificate and a certificate of business operation on veterinary medicines;
3. Supply an authorized letter and a registration certificate from the manufacturers of veterinary medicines from the exporting country if the veterinary medicines are imported;
4. Supply an authorized letter and identification card of a representative if a third person requests for a registration;

5. Labels and prescription documents of veterinary medicines;
6. Samples or ingredients of veterinary medicines as quantified by the Department of Livestock and Fisheries;
7. Supply evidence that shows technical information on quality, safety and efficiency of the medicines;
8. Supply details on veterinary medicines that indicates name, mode, severity, volume, character of the veterinary medicines as well as indicate name, quantity of important medicines and ingredients in the medicine formula;
9. Other important documents as requested by the Department of Livestock and Fisheries, Ministry of Agriculture and Forestry.

Article 16 Detail of the Veterinary Medicines Requested for Registration

Detail of veterinary medicines requested for registration must be written in Lao and English as following:

1. Name of medical formula or name of veterinary medicines;
2. Commercial name;
3. Main ingredients;
4. Production process;
5. Medical registration number from the manufacturing country (if the medicines are registered in foreign countries already);
6. Benefits;
7. Usage, storage, period of stop using medicines and warnings;
8. Name and address of manufacturers, processors or containers or distributors;
9. Other necessary information by types of medicines.

Article 17 Discretion to Issue a Certificate of Veterinary Medicines

After the Department of Livestock and Fisheries receive a request letter and documents for registration for veterinary medicines, compliance checking must be conducted with 5 official working days.

In the event of ineligibility to register, authorities must notify registration requesters in a written manner.

Certificate on the registration of veterinary medicines is forever valid.

Article 18 Changes on the Certificate of Veterinary Medicines

A certificate holder with the intention to make any changes to the registration must propose a letter to the Department of Livestock and Fisheries to do so in a written manner.

Article 19 A Stop of the Certificate on Veterinary Medicines

Registration certificate of the veterinary medicines will be stopped in the following cases:

1. As proposed by the requester of the certificate;
2. A registered veterinary medicines without any operation, production or import within two years;
3. A registered veterinary medicines used in other intention not conform to the registration.

Article 20 Withdrawal of the Registration Certificate

A certificate of veterinary medicines will be terminated in the following cases:

1. A terminated certificate without improvement or edit;
2. A certificate from the originating country is terminated;
3. Produced or imported veterinary medicines that are found and proved to have severe impact on the health of animals, aquatic animals and users or counterfeit medicines.

The Department of Livestock and Fisheries must delete such registration from the list of veterinary medicines and inform the matter to the public.

Article 21 A Proposal or an Appeal to the Termination or Withdrawal of a Registration Certificate of Veterinary Medicines.

Persons with a termination or a withdrawal status can propose or appeal in a written manner to the Ministry of Agriculture and Forestry within specified time of 30 days from the day the termination or withdrawal of a registration certificate of veterinary medicines becomes effective for consideration in the event that compliance with conditions regulation is correct and complete.

Chapter 4 Standard and Safety of Veterinary Medicines

Article 22 Standard of Veterinary Medicines

Standard of veterinary medicines are the specific characteristics of the veterinary medicines in terms of quality and quantity that are enough to prevent and cure animals and aquatic animals according to their types, weight and age to determine the application of manufacturers and users.

The Ministry of Agriculture and Forestry determines the standard and ingredients of veterinary medicines in collaboration with the Ministry of Health to form the foundation of monitoring, inspection, certification and registration of the veterinary medicines.

Article 23 Safety of Veterinary Medicines

The safety of veterinary medicines is measures used to protect health of animals and users, which include the following:

1. The production of veterinary medicines;
2. Containers and packaging;
3. Labeling and prescription;
4. Transport and storage;
5. Training of human resources;
6. Advertising;
7. Dappling and analyzing;
8. Import;
9. Export'
10. Transit;
11. Sales;
12. Use;
13. Unsafe veterinary medicines;
14. Recall of veterinary medicines.

Article 24 the Production of Veterinary Medicines

Prior to the production of veterinary or ingredients of veterinary medicines, persons with permission to run business on veterinary medicines must conform to the following measures:

1. Operating the production of veterinary medicines in accordance with good production standard and/or be produced with risk analyzing system and with control of dangerous points;
2. Plant, machines, tools must be designed, constructed and stalled systematically to assure it facilitates operation and avoid contamination;
3. Water used in the production must be clean and meet the standard set by relevant agency, water tank and water pipes must be made of safe materials;
4. Machines, equipment used with or ingredients of veterinary medicines must be dry cleaned every time after and before the use to protect fungi and ၎ံ့ခဲးခဲး from happening;

5. Mixing machines, scales and other equipment used in producing veterinary medicines must be proper for quantity, volume or ingredients of veterinary medicines by strictly following good hygiene and inspecting clarity in accordance with regulations set by technology and sciences sector;
6. Have storage system and effective waste water treatment;
7. Prior to the production for sales, the products must be registered with the Department of Livestock and Fisheries, Ministry of Agriculture and Forestry and must be produced accurately by the registered medical formula;
8. Be under the management of operators and implementers designated and acknowledged only by organization managing veterinary medicines;
9. Prior to the sales of each set of veterinary medicines produced, analysis, quality certification and the collecting of certificate documents within three years must be conducted.

Article 25 Containers and Packaging of Veterinary Medicines

Containers and packaging of veterinary medicines must be durable, proper to be used with different shapes of medicines and be sealed.

Article 26 Labels and Documents Prescribing Veterinary Medicines

Veterinary medicines must be labeled and prescribed in images or printing with clear Lao and English affixed, typed or contained in the containers with the following messages:

1. Name and address of manufacturing location, import or sales;
2. Registration number of veterinary medicines;
3. Mark or trade mark affixed on containers;
4. General and commercial names;
5. Modes;
6. Benefits;
7. Main ingredients in the formula;
8. Weight and volume contained;
9. Number of manufacturing sets, date of manufacture and expiration;
10. Use, storage and warnings.

Article 27 Transports and Storage of Veterinary Medicines

Business operation license holders on veterinary medicines must transport and store in accordance with instruction made by manufacturers and/or by technical standard as specified by the Ministry of Agriculture and Forestry.

Article 28 Training of Human Resources

Business operation license holders on veterinary medicines on the production, import, export and sales of veterinary medicines must have plans to train human resources working at the production plant, warehouse, transport, distribution and sales of the veterinary medicines periodically to build understanding on the protection and prevention of degraded medicines.

Article 29 Advertisements of Veterinary Medicines

The advertisement of veterinary medicines must follow the permitted content, methodology and locations. The content of advertisement must be clear, accurate with characteristics, quality and avoid advertisements that exaggerate and deceive people to believe.

Article 30 Samples and Analysis of Veterinary Medicines

Manufacturers of veterinary medicines, their ingredients and substances must conduct sample collection and analyze at the veterinary laboratory room that meet standard and coherent with principles, procedures and methodology as specified by the Ministry of Agriculture and Forestry.

Agriculture and forestry sector must collect samples and analyze veterinary medicines manufactured, imported, sold or exported to monitor and inspect the quality of medicines periodically.

In case of having the necessity to send samples of veterinary medicines to be analyzed in foreign countries, such laboratory rooms have to satisfy international standard and acknowledged by the Ministry of Agriculture and Forestry.

Article 31 Imports of Veterinary Medicines

The imports of veterinary medicines must follow the following practices:

1. Must request for a license to operate the import business and register the medicines as required by this Decree;
2. Assure the safe containers of packaging, labeling, storage and transport;
3. Assure the quality as registered;
4. Import through ports of customs as specified in import license and be inspected by veterinarians at the border;
5. Store the samples in accordance with techniques;
6. Practice the procedures, conditions and standard of the Ministry of Agriculture and Forestry as set out periodically.

Article 32 Exports of Veterinary Medicines

The exports of veterinary medicines must follow the following practices:

1. Must request for export business license and be registered in accordance with this Decree;
2. Perform other relevant laws and regulations of Lao PDR;
3. Perform the conditions and regulations set by importing and transiting country;
4. Export through ports of customs as specified in the export license and be inspected for accuracy from veterinarians at borders.

Article 33 Transits of Veterinary Medicines

Transiting of veterinary medicines must follow the followings:

1. Must request for a transit permit for the veterinary medicines as specified in this Decree;
2. Perform relevant laws and regulations of Lao PDR, bilateral and multilateral agreements which Laos is a member of;
3. Perform the conditions and regulations set by exporting and importing country
4. Transit through ports of customs as specified in the transit permit and must be inspected for accuracy by veterinarians at borders;
5. Assure the safe transport and use specified transport route. In the event of having necessity to transship or unload the goods at warehouse before, such practice must be inspected, certified by veterinarians at exporting border.

Article 34 Sales of Veterinary Medicines

The sales of veterinary medicines must be conducted as following:

1. Must request for a license to sell veterinary medicines;
2. Assure the safe packaging, labeling and transport of veterinary medicines;
3. Store veterinary medicines in accordance with techniques;
4. Sell high quality, safe and coherent with formula of veterinary medicines as registered and permitted;
5. Sales must be under the management of operators and be accurate with medical formula as specified in regulations and license;
6. Sell the prescription only veterinary medicines and be sold by operators at the pharmacy;

7. Prescription of veterinary medicines to be sold or distributed must be conducted by people holding technical license only;
8. Retail sales of veterinary medicines is not allowed to lessen the quantity of medicines and sell them by themselves;
9. Provide cooperation to veterinarians in inspecting the quality of veterinary medicines.

Article 35 Uses of Veterinary Medicines

Veterinary medicines must be accurately used in accordance with laws, be responsibly, carefully, reasonably and strictly conform to the instruction of veterinarians or manufacturers.

Article 36 Unsafe Veterinary Medicines

Unsafe veterinary medicines are counterfeit or degraded medicines, veterinary medicines that do not satisfy standard.

If the production, import, sales or transit of unsafe veterinary medicines are found, Ministry of Agriculture and Forestry must conduct the followings:

1. Stop the production, import, sales or transit in written form or to practice other measures in accordance with laws and regulations;
2. Recall the unsafe veterinary medicines and let the manufacturers, importers, sellers and transit conductors be responsible for expenses occurred from the recall or the destruction;
3. Publicize to the public about the unsafe veterinary medicines.

Article 37 The Recall of Veterinary Medicines

In the event of found unsafe veterinary medicines, agriculture and forestry is to issue written orders to the holders of business on the production, import, export and sales as well as proceed to apply measures to recall or instruct the destruction and elimination.

The elimination and destruction of veterinary medicines are to be conducted in accordance with regulations as specified by the Ministry of Agriculture and Forestry.

Chapter 5

Veterinary Antimicrobials for Animals and Aquatic Animals

Article 38 Veterinary Antimicrobials for animals and aquatic animals

Veterinary Antimicrobials for animals and aquatic animals are the medicines extracted from living things or artificial with activation that can stop the growth of diseases or cure pathogen such as plaque (microorganism, bacteria), virus, parasite, mushroom infection.

Article 39 List of Antimicrobials

Ministry of Agriculture and Forestry determines the important, very important and the most important list of antimicrobials used to protect health of animals and aquatic animals in accordance with instruction of the World Organization for Animal Health and disseminate through media platform to the public.

Article 40 Principles on the Use of Antimicrobials

The use of antimicrobials must conform to the following principles:

1. Use as necessary under veterinary prescription;
2. Use the registered and permitted veterinary medicines;
3. Use in accordance with diseases;
4. Use in accordance with quantity as specified in label with the accurate calculation of quantity used;
5. Use accurately;

6. Use accurately with sick animals and aquatic animals as prescribe;
7. Use in the proper time manner to maintain constant dose in animals and can be activated to stop or adequately destroy microbial and must be used within specified time.

Details on the management and use of antimicrobials for animals and aquatic animals are specified in a separate regulation.

Chapter 6

Business Operation on Veterinary Medicines

Article 42 Types of Business on Veterinary Medicines

Business types on veterinary medicines are the followings:

1. Production of veterinary medicines,
2. Analysis of veterinary medicines;
3. Import, export and transit of veterinary medicines;
4. Sales of veterinary medicines;
5. Business on veterinary medicines as stipulated by the Ministry of Agriculture and Forestry.

Article 43 Veterinary Medicines Exempted for Business License

Veterinary medicines that are exempted for business permit are the followings:

1. Veterinary medicines of the governmental agency that are produced for laboratory research;
2. Imported veterinary medicines with the purpose to promote, study, test or for other advantages as agreed by the government, but not for sales;
3. Samples of veterinary medicines imported to register;
4. Veterinary medicines that are from traditional medicines without commercial purpose.

Processors or Importers of the exempted veterinary medicines must report and notify the medical formula as required by the agriculture and forestry section.

Article 44 Conditions on Veterinary Medicines for Business Operators

Individual, legal entity and organization with the intention to operate a business on veterinary medicines must meet the following conditions:

1. Have capital, office, buildings, equipment, vehicles;
2. Have veterinarians holding a minimum of a bachelor's degree level and experience on veterinary medicines for more than two years, have pharmacists with knowledge and experience to distribute veterinary medicines and adequate human resources to run businesses on other veterinary medicines;
3. Never violate regulation on medicines, veterinary medicines or narcotics;
4. Be healthy;
5. Other conditions as specified by the Ministry of Agriculture and Forestry.

Article 45 Documents Required for a permission

Documents required for a permission to operate a business are the followings:

1. A request letter as specified by the Department of Livestock and Fisheries;
2. A copy of Identification card or a family book, an authorized letter as a representative in the event that a third person requests for it;
3. A copy of business certificate or an investment permit;
4. Economic-technical study or a program proposal or project;
5. Environmental certificate from the natural resources and environment sector;
6. Other necessary documents as required by the agriculture and forestry sector.

Article 46 Consideration to Business Operation on Veterinary Medicines

After the agriculture and forestry sector has received accurate and complete documents with the inspection of location has been passed, a consideration to issue a business operation permit on the veterinary medicines must be granted in accordance with the level of management as followings:

Ministry of Agriculture and Forestry consider the followings:

1. The production and analysis of the ingredients of veterinary medicines;
2. Import, export and transit of veterinary medicines;
3. Sold and prescribed veterinary medicines by veterinarians;
4. Veterinary medicines sold and distributed at a drug store;
5. Whole sales of veterinary medicines.

Provincial Department of Livestock and Fisheries consider the followings:

1. Import and export of veterinary medicines that are sold or distributed only by authorized dealers and for general sales
2. Retail sales.

Consideration giving to issue business operation license on veterinary medicines must follow in the following time frame:

1. 20 official working days for the production and analysis of veterinary medicines;
2. 15 official working days for import, export, transit and sales.

In the event of unsuccessful permit to business operation within the given time, a written notification stating reasons must be sent to the requester.

Ministry of Agriculture and Forestry determines the form of business license on veterinary medicines.

Article 47 Application of Business License

The use of business license on the production, import, export, sales and transit of veterinary medicines must be practiced in accordance to different cases of business types.

Validity of a business license on veterinary medicines are as following:

1. A business license on the production of veterinary medicines is valid for three years;
2. A business license on the export of veterinary medicines is valid for two years;
3. A business license on the import, sales and transit of veterinary medicines is valid for one year.

Thirty days prior to issuing a business license on veterinary medicine's invalidity, a license holder must submit a proposal letter to organization managing the issuance of license using the form as created by the Ministry of Agriculture and Forestry. A consideration to renew the license or not must be made within fifteen days from the day a proposal letter is received.

In the event of damage or destroy of a license, a license holder must immediately notify to organization issuing the license by compiling re-applying for a license within fifteen days from the day the license is damaged or destroyed.

Article 48 Rights and Duties of a License Holders on Veterinary Medicines

Receivers of business license on veterinary medicines are obliged the following rights and duties:

1. Must strictly run their business in accordance with the permission, technical standard and laws;
2. Recruit operators and implementers in accordance with quantity and conditions as specified by the Ministry of Agriculture and Forestry;

3. Be the lead in keeping safety, using relevant measures to stop unsafe veterinary medicines that impact on people, animals, environment as well as be responsible for loss caused by business operation;
4. Put a sign board at the operating location that is clearly visible to the public;
5. Provide knowledge training to human resources to raise awareness and understanding on the responsibility and the quality storage and the safety of veterinary medicines;
6. Create a recording system and database on the production, test, import, export and sales as well as keep the data for at least three years;
7. Provide cooperation, information supply and facilitation to officers and veterinarians;
8. Contribute fund or labors in the quality development of veterinary medicines;
9. Pay fees, services fee and other duties as specified by relevant law and regulation;
10. Receive information on the work of veterinary medicines;
11. Fairly assure policy protecting rights as stipulated by laws;
12. Make a request to organization holding rights on the violation made by officers and veterinarians.

Article 49 Relocation, Termination and Transfer of Business

Receivers of a business license on veterinary medicines with the intention to move the production plant, warehouse or stores or terminate the business must inform to agriculture and forestry sector in a written manner within fifteen days prior to the move or termination of business as well as must sell or use the all of the veterinary medicines within ninety days from the day receivers receive a notification to stop the business onwards.

A receiver of the transfer is also obliged to paying duties as the transfer maker.

Article 50 Termination of Business

The operation of business on veterinary medicines will be terminate according to the following conditions:

1. As proposed by business operators;
2. Not conform to a warning made by organization managing and inspecting veterinary medicines to adjust the operating conditions, technical standard and quality of the business operation;
3. Run a business that is not conform to what is permitted.

Article 51 Termination of Business Operation License

Business operation on veterinary medicines will terminated in the event that license holders do not perform the conditions, technical standard, quality of the business operation within the given time in the notification to stop.

Veterinary medicines or their ingredients of the holder of the withdrawn license can fully be sold or handed over to other people within ninety days from the official day of the notification to stop.

Article 52 a proposal or an appeal to terminate or withdraw business operation license

Individuals, legal entity or organization that is terminated or withdrawn their business operation license on veterinary medicines can propose or make an appeal to upper organization of the organization that notifies such termination or withdrawal to consider terminate if compliance of condition or regulation can be accurately proven or can supply scientific evidence which guarantees reasons of such termination or withdrawal are inaccurate by truth.

Article 53 Prohibitions for Receivers of Registration and Business License on Veterinary Medicines

Receivers of registration and business license on veterinary medicines are prohibited from these following habits:

1. Run a business at the prohibited location;
2. Produce, import, export and sales of unsafe veterinary medicines, unregistered or withdrawn veterinary medicines;
3. Imitate veterinary medicines that are already registered;
4. Sell unlisted, low standard, expired and degraded quality medicines;
5. Transfer or lend business certificate or license;
6. Give to people without official permission which is lacking technical knowledge;
7. Use dangerous or prohibited substances mixed in veterinary formula;
8. Use unsafe or improper containers and packages;
9. Display the medicines with dangerous substance to animals or transport the medicines not in accordance with specified condition;
10. Distribute unpackaged, unlabeled veterinary medicines as registered;
11. Imitate or disseminate detail of the registration for economic benefits or cause damages to the reputation of the registers;
12. Inaccurately or over advertisement of veterinary medicines;
13. Scare, violate and use improper words with officers or authorities;
14. Refuse to take responsibility, avoid, swerve or hide from the inspection of officers;
15. Bribe officers or take a part to corrupt the government and users of veterinary medicines;
16. Other behaviors that violate laws.

Article 54 Prohibition for government officers and veterinarians

Government officers and veterinarians are prohibited from the following behaviors:

1. Use the right, duty, position, violence, force, scare to seek for personal benefits or for family, cousins and their people;
2. Ask for, request, receive bribery from individuals, legal entity and other organization;
3. Careless, unaware, ignore, irresponsible the conduct of work;
4. Oppress, drag, fake, and issue documents that are inaccurate or destroy the documents;
5. Call for fees and service fees not specified in laws;
6. Disseminate the governmental or official, individual, legal entity or organization secrets;
7. Deceive the truth, hide and protect or join violators;
8. Other behaviors that violate laws.

Article 55 Prohibitions to Use Veterinary Medicines

Users of veterinary medicines are prohibited from the following behaviors:

1. Advertise to excuse of conduct any behaviors that can cause damages to the license issuers;
2. Use unregistered veterinary medicines or not instructed by manufacturers or veterinarians;
3. Other behaviors that violate laws.

Chapter 8 Management and Inspection of Veterinary Medicines

Article 56 Organizations Managing and inspecting the Work of Veterinary Medicines

Government centrally and unity manages and inspects the work of veterinary medicines across the country by designating the direct responsibility to the Ministry of Agriculture and Forestry to be the central in collaborating with ministries, organizations and local administrations.

Organizations managing and inspecting the work of veterinary medicines include:

1. Ministry of Agriculture and Forestry with the Department of Livestock and Fisheries as a secretary;
2. Provincial Department of Agriculture and Forest with the livestock and fisheries sector as a secretary;
3. District offices of agriculture and forestry with the livestock and fisheries unit as a secretary.

Article 57 Rights and Duties of the Ministry of Agriculture and Forestry

Ministry of Agriculture and Forestry holds the rights and duties as following:

1. Study to create policy, strategic plans, laws and regulations on the work of veterinary medicines to propose to the government to consider;
2. Turn policy, strategic plans, laws and regulations on the work of veterinary medicines into plans, work plans, projects and regulations for the implementation;
3. Advertise, disseminate policy, strategic plans, laws and regulations, plan, work plan, project on the work of veterinary medicines;
4. Permit the establishment, stop or withdraw business operation permit on the work of veterinary medicines;
5. Register, list out, certify the good standard of production on the veterinary medicines;
6. Issue, stop or terminate decision, order, instruction or notification on the work of veterinary medicines;
7. Monitor, inspect the implementation of the work of veterinary medicines by collaborating with relevant agencies and local administrations;
8. Designate veterinarians to productively and effectively help develop, inspect, monitor the work of veterinary medicines;
9. Train human resources as well as raise awareness in all sector in society on the work of veterinary medicines by collaborating with relevant agencies and local administrations;
10. Receive and consider the solution to a proposal from individuals, legal entity or organizations on the work of veterinary medicines;
11. Cooperate and collaborate with ministries, internal and international organizations on the work of veterinary medicines;
12. Summarize and report the implementation of the work of veterinary medicines to the government periodically;
13. Use the rights and other duties as specified by laws and regulations.

Article 58 Rights and Responsibilities of the Provincial Department of Agriculture and Forestry

Provincial Department of Agriculture and Forestry has rights and duties as following:

1. Turn policy, strategic plan, laws, regulation on the work of veterinary medicines into implementation;
2. Advertise, disseminate policy, strategic plans, laws, regulations on the work of veterinary medicines for public awareness and understanding;
3. Permit the establishment, stop of withdraw business operation certificate on veterinary medicines;
4. Issue, stop or terminate decisions, order, instructions and notification on the veterinary medicines;
5. Monitor and inspect the implementation of the work of veterinary medicines by collaborating with relevant agencies and local administrations;
6. Designate veterinarians to help develop, inspect, monitor the work of veterinary medicines;

7. Train human resources as well as raise awareness in all sector in society on the work of veterinary medicines by collaborating with relevant agencies and local administrations;
8. Promote, monitor and evaluate the implementation of the work of veterinary medicines of the district offices of agriculture and forestry;
9. Receive and consider the solution to a proposal from individuals, legal entity or organizations on the work of veterinary medicines;
10. Collaborate with departments, offices at provincial and district level and other relevant agencies in implementing the work of veterinary medicines;
11. Regularly summarize and report on the implementation of veterinary medicines to the Ministry of Agriculture and Forestry and provincial and capital administrations;
12. Use rights and other duties as specified by laws and regulations.

Article 59 Rights and Duties of District Offices of Agriculture and Forestry

District Offices of Agriculture and Forestry has t rights and duties as following:

1. Implement policy, strategic plan, laws, regulation on the work of veterinary medicines;
2. Disseminate policy, strategic plans, laws, regulations on the work of veterinary medicines for public awareness and understanding;
3. Permit the establishment, stop of withdraw business operation certificate on veterinary medicines;
4. Issue, stop or terminate decisions, order, instructions and notification on the veterinary medicines;
5. Monitor and inspect the implementation of the work of veterinary medicines by collaborating with relevant agencies and local administrations;
6. Request training for human resources as well as raise awareness in all sector in society on the work of veterinary medicines;
7. Propose to provincial department of agriculture and forestry to consider designate or rotate officers, veterinarians in district level;
8. Receive and consider the solution to a proposal from individuals, legal entity or organizations on the work of veterinary medicines;
9. Collaborate with other relevant agencies in implementing the work of veterinary medicines;
10. Regularly summarize and report the implementation of the work of veterinary medicines to the provincial department of agriculture and forestry, chief of district, head of community and governors;
11. Use rights and other duties as specified by laws and regulations.

Article 60 Rights and Duties of Agencies and Other Sector

Agencies and other sector have rights and duties to collaborate with agriculture and forestry sector according the roles and responsibility to implement policy, strategic plans, laws and regulations on the work of veterinary medicines with productivity and efficiency aiming at managing veterinary medicines to meet quality, safety and proper to prevent and cure diseases in animals and aquatic animals.

Article 61 Rights and Duties of Veterinarians

Veterinarians are officers from the Department of Livestock and Fisheries, Provincial Department of Agriculture and Forestry, District Offices of Agriculture and Forestry are to implement the work on veterinary medicines as following:

1. Disseminate policy, strategic plan, laws and regulation on the work of veterinary medicines for awareness and understanding of the public and all sectors;
2. Inspect the production plant, research center, import export, transit, stores, warehouse, vehicles and locations that use veterinary medicines;

3. Research, seize, confiscate unlicensed, low standard, expired or unregistered veterinary medicines as well as to propose to organizations and relevant authorities to apply necessary measures such as an order to stop for investigation at location or target of suspect;
4. Fine violators of laws and regulations on the veterinary medicines as well as notify warnings to violators;
5. Receive, record cases, require for documents and inspect the documents and initial sentences with violence on the laws of veterinary medicines;
6. Collect samples of veterinary medicines to used as evidence and analysis;
7. Educate violators of laws and regulations on the work of veterinary medicines;
8. Summarize the result of inspection and compile documents to organizations managing veterinary medicines or investigations officers to solve or prosecute according to laws;
9. Use rights and other duties as specified by laws and regulations.

Article 62 Content of Inspection

Inspection of veterinary medicines must include the following content:

1. Compliance with laws and regulations on veterinary medicines;
2. Implementation of authorities and veterinarians;
3. Business operation on the production, import, export, transit and sales of veterinary medicines of people holding technical license including the use of animals feeds of the owners of animals;
4. Create and implement work plan on veterinary medicines.

Article 63 Inspection Modes

Inspection of veterinary medicines must follow these three modes:

1. Regular inspection is the inspection that is regularly conducted with time is precisely specified.
 2. Inspection with advanced notification is the inspection that is not planned before in necessary circumstances by informing the person of inspection in advance;
 3. Immediate inspection is the urgent inspection without advanced notification.
- Inspection must strictly follow laws.

Chapter 9

Incentives for Contributors and Measures for Violators

Article 64 Incentives for Contributors

Individuals, legal entity or organization with outstanding results in implementing this decree such as business operation on veterinary medicines that receive technical standard, quality and safety will be praised or provided with other incentives as specified in regulations.

Article 65 Measures for Violators

Individuals, legal entity or organization violating this decree such as prohibitions, which is criminal misconduct that causes damages without sincere report, will be punished according to the laws on governmental officials.

Article 66 Education Measures

Individuals, legal entity or organization violating this decree such as prohibitions that are mild will be warned and educated.

Article 67 Professional Measures

Authorities and governmental officials who violate this decree such as prohibitions which are not criminal misconducts, cause damages and sincere to report will be applied with professional measures according to the law on governmental officials.

Article 68 Fine

Individuals, legal entity or organization violating this decree will be fined as following:

1. Run a business on veterinary medicines without license and was educated on the matter before, but still conduct the repetitive guilt will be fined by 25 percent of the value of veterinary medicines and such veterinary medicines will be stopped and confiscated;
2. Produce, import, export and sell unregistered, withdrawn veterinary medicines with education on registration has been provided already, but did not improve, will be fined by 40 percent of the total value of veterinary medicines and such veterinary medicines will be stopped and confiscated;
3. Produce, import, export and sell veterinary medicines that don't meet standard, are degraded in quality will be fined by 60 percent of the total value of veterinary medicines and such veterinary medicines will be stopped and confiscated;
4. Produce, import, export and sell fake veterinary medicines that have unwanted substances with proof to have negative impact on the health of animals and users will be fined by one time of the total value of veterinary medicines and with such veterinary medicines be stopped and withdrawn from business operation license.

Article 69 Civic Measures

Individuals, legal entity or organization violate this decree and cause damages to the collective benefit of the government, crowd, society or other individuals will be paid for such damages caused by.

Article 70 Criminal Measures

Individuals, legal entity or organization violate this decree which is a criminal misconduct will be punished according to laws based on the degree of cases.

Chapter 10 Final Provision

Article 71 Implementation

Ministry of Agriculture and Forestry is designated to collaborate with other relevant agencies to effectively implement this decree.

Ministries, organizations, local administration and other relevant sector be informed to strictly practice the decree.

Article 72 Effectiveness

This Decree becomes effective after signing and publicizing in the Lao Official Gazette in fifteen days.

Regulations and provision against this Decree will be terminated.

**Rep. Government of Lao PDR
Prime Minister**