A PROCLAMATION TO PROVIDE FOR VETERINARY DRUG AND FEED ADMINISTRATION AND CONTROL

WHEREAS, it is found necessary to regulate the proper production, distribution and use of veterinary drugs to ensure safety, efficacy and quality of the products and to enhance the productivity and health of the livestock population;

WHEREAS, it is becoming increasingly important to improve the overall performance of the animal health program to remain competitive in the international market for animal and animal products;

WHEREAS, it is found necessary to strengthen the administration of feed to increase the development of the feed industry and animal production and thereby enhance public health safety;

WHEREAS, it is found essential to prevent animal diseases emanating from poor quality and safety of animal feeds to improve the overall productivity and health of the livestock population;

WHEREAS, it is found necessary to prevent and control the illegal production, distribution and use of veterinary drugs and feed;

WHEREAS, to achieve these ends, it is found necessary to establish an effective system of veterinary drug and feed administration and control;
NOW, THEREFORE, in accordance with Article 55(1) of the Constitution of the Federal Democratic Republic of Ethiopia, it is hereby proclaimed as follows:

PART ONE

GENERAL

1. Short Title

This Proclamation may be cited as the “Veterinary Drug and Feed Administration and Control Proclamation No. 728/2011.”

2. Definitions

In this Proclamation unless the context otherwise requires:

1/ “animal” means includes domestic and wild animals, birds, aquatic animals, bees and silkworm;

2/ “veterinary drug” means any substance or mixture of substances used in the diagnosis, treatment or prevention of animal disease, and includes products used to treat against internal and external parasites and disease transmitting vectors, biological products, sanitary items and veterinary instruments;

3/ “biological product” means reagents, sera, attenuated or killed vaccines or microbial genetic material used for the diagnosis, prevention or treatment of animal disease;

4/ “veterinary instrument” means any instrument that may be used for diagnosis or treatment of animal disease, and includes laboratory, artificial insemination and castration instruments;

5/ “traditional veterinary drug” means a veterinary drug developed by custom, accepted by the society and its efficacy is tested;

6/ “complementary or alternative veterinary drug” means a veterinary drug which is not associated with traditional or modern veterinary drug and used as complementary or alternative drug;
7/ “germ” means any disease causing agent including virus, bacteria, fungus, protozoa, internal and external parasites;

8/ “pharmacovigilance” means examination of adverse effects of any veterinary drug-related problem based on the collection of information from animal health professionals and animal owners;

9/ “veterinary drug trade” means profit oriented production, repacking, import, export, whole sale or retailing of veterinary drugs and includes veterinary drug quality control laboratory service and acting as commercial agent;

10/ “feed” means material used as animal feed and produced or processed for commercial purpose;

11/ “feed additives” means nutritional or non-nutritional ingredient added in small quantity during feed processing;

12/ “feed trade” means profit oriented processing, packing, import, export, wholesale or retail of feed and includes feed quality control laboratory service and acting as commercial agent;

13/ “certificate of competence” means a certificate issued by the appropriate organ to verify that a person meets the criteria set by the Authority to engage in veterinary drug or feed trade;

14/ “packing material” means any material used for filling, inserting or wrapping veterinary drug or feed;

15/ “label” means any material which is printed or affixed to a packing material which provides the necessary information about a veterinary drug or feed and includes an explanatory note attached therein;
16/ “counterfeiting” means using the packing material, trade name, trademark or any special mark of an authentic product of a manufacturer and presenting such falsely packed and labeled veterinary drug or feed as if it is manufactured by the genuine manufacturer;

17/ “adulteration” means reducing the quality of a veterinary drug or feed by adding to its content a substance other than its content, or by substituting its content in whole or in part by such other substance, or by processing or storing it under unhygienic conditions whereby it is contaminated with any other foreign matter;

18/ “pre-clinical trial” means documentary evaluation, physical inspection and laboratory assessment of veterinary drug, feed or feed additive;

19/ “clinical trial” means testing a veterinary drug on animal to prove its efficacy and safety;

20/ “veterinary drug professional” means a veterinarian or animal health assistant, or a pharmacist, druggist or pharmacy technician engaged in providing professional service in relation to veterinary drugs;

21/ “veterinarian” means a person graduated with doctorate degree or above in veterinarian profession from a recognized university;

22/ “other animal health professionals” means a person graduated with BSc degree or diploma or certificate in veterinarian profession from a recognized institution;

23/ “professional license” means certificate issued by the appropriate organ to veterinary drug professional or to animal feed professional to carry on his profession;

24/ “veterinary pharmacy” means a facility solely used for the sale of veterinary drugs;
### Scope of Application

1) This Proclamation shall be applicable to regulatory activities in respect of veterinary drugs, feed and veterinary drug professionals.
2/ Without prejudice to sub-article (1) of this Article, the application of this Proclamation at the federal level shall be in respect of:

   a) setting standards in relation to veterinary drugs, feed and veterinary drug professionals; and

   b) regulating trans-regional veterinary drug and feed production, distribution, promotion, storage and quality control and veterinary drugs and feed import and export activities.

3/ Without prejudice to the generality of sub-article (2) of this Article, regulatory activities other than those given to the Authority under Article 20 of this Proclamation shall be carried out by regional state regulatory bodies.

**PART TWO**

**VETERINARY DRUG ADMINISTRATION AND CONTROL**

4. Registration

1/ No veterinary drug may be produced locally or imported and put in use unless it is registered by the Authority after being tested for its safety, efficacy and quality.

2/ Notwithstanding sub-article (1) of this Article, the Authority may authorize, in compelling circumstances of natural disaster causing high animal migration such as drought, flood and earth quick, or in cases of epidemic of exotic animal disease, or for animal health research, or for pre-registration test.

5. Certificate of Registration

1/ Certificate of registration of a veterinary drug shall be valid for five years.

2/ A certificate of registration of a veterinary drug may be renewed every five years where the drug continues to meet the requirements of registration.
3/ An application for renewal of a certificate of registration shall be submitted three months before the expiry of the validity period.

6. Quality Standards and Use of Veterinary Drugs

1/ Any veterinary drug or raw material or packing material of veterinary drug shall meet the requirements prescribed in the quality standards issued or adopted by the competent organ.

2/ Any veterinary drug shall be available for use in accordance with the guidelines issued by the Authority to ensure judicious use of veterinary drugs.

7. Post Marketing Surveillance

1/ The Authority shall carry out post marketing surveillance with a view to assessing the resulted benefit and damage of registered veterinary drugs.

2/ The holder of the certificate of registration shall supply to the Authority the pharmacovigilance information that he possesses relating to the veterinary drug during the post market surveillance.

3/ The use of a veterinary drug shall be banned and its registration shall be suspended or revoked where, the findings of a post marketing surveillance proves that:

a) it lacks the expected safety, efficacy or quality for the intended use;

b) its risk outweighs its benefit; or

c) its withdrawal period and residue in the treated animal does not comply with national or international requirements.
8. Pre-Clinical and Clinical Test

1/ The Authority may take sample, peruse document, conduct physical examination and carry on pre-clinical laboratory examination to assess safety, efficacy and quality of any veterinary drug to be produced locally or imported.

2/ A clinical test on animals shall be conducted on the basis of authorization by the Authority and with the consent of the owner, and on wild animals, when authorization of the Authority and the Ethiopian Wildlife Development and Conservation Authority is obtained.

3/ Clinical test shall be conducted with due care to animal welfare requirements.

9. Packaging and Labeling

1/ Any producer, importer or distributor of veterinary drug or a veterinary pharmacy may not supply a drug to the market or dispense it otherwise unless it is duly packed and labeled.

2/ The label of any veterinary drug shall be written either in the Amharic or English language and includes the statement "for veterinary use only" in a conspicuous manner.

10. Prescription and Dispensing of Veterinary Drugs

1/ Veterinary drug shall only be prescribed by a veterinarian. Traditional veterinary drug shall be prescribed and dispensed by traditional veterinary drug practitioner registered and recognized by the Authority.

2/ A veterinarian shall prescribe veterinary drugs following prescription procedures and on standard prescription paper.

3/ Veterinary drug shall only be dispensed by a veterinary drug professional holding professional license.
4/ Any veterinary drug professional shall dispense veterinary drugs with care by providing sufficient information and awareness based on dispensing procedures.

5/ Notwithstanding the provisions of sub-article (1) and (2) of this Article, the Authority may, by directive, issue the list of veterinary drugs that may also be prescribed by animal health professionals other than veterinarians and those which could be dispensed without prescriptions.

11. Veterinary Biological Products

Without prejudice to other provisions of this Proclamation the Authority may ban the production, importation and distribution of a veterinary biological product on the following grounds:

1/ the product contain germ or germ genetic material that causes a disease which is considered exotic to Ethiopia;

2/ the product is derived from infected tissues of animal and suspected to be a significant risk to spread disease in the country;

3/ use of the product may not be in the best interest of or may cause negative impact in veterinary or public health control or survey program of the country; or

4/ use of the product may have negative impact on the country’s export trade in animal, animal products and by-products.

12. Veterinary Drug Trade

1/ No person may engage in veterinary drug trade without obtaining a certificate of competence from the appropriate organ.

2/ No person may operate a veterinary pharmacy in the absence of a veterinary drug professional holding a professional license.
### Traditional and Complimentary or Alternative Veterinary Drugs

1. Any locally produced or imported traditional, complimentary or alternative veterinary drug may not be put into use unless assessed and registered by the appropriate organ.

2. No person may manufacture, import, export, distribute or sell traditional, complementary or alternative veterinary drug without obtaining a certificate of competence from the appropriate organ.

### PART THREE
Feed Administration and Control

14. Feed Quality Standards

No feed or feed additive may be put into use unless it is ascertained by the appropriate organ that it complies with the quality standards issued or adopted by the competent organ.

15. Feed Safety Control

1. Any feed, feed raw material or additive shall be produced, stored and transported in a manner which prevents contamination and deterioration.

2. Without limiting the generality of sub-article (1) of this Article:

   a) feed and feed raw materials and additives processing plants and storage and transportation facilities shall be kept clean and effective pest control programs shall be implemented;

   b) containers and equipments used for processing, storage, transport, handling and weighing feed and feed raw materials and additives shall be kept clean;

   c) cleaning programs may be effective and minimize residues of detergents and disinfectants;
d) any feed processing facility may not be close to feedlot or fattening or slaughter house;

e) any feed shall be free from minerals, ingredients and pathogens which are dangerous to the health and safety of animals.

16. Packing and Labeling

1/ Any producer, importer or distributor of feed or a feed shop may not supply feed to the market or distribute it otherwise unless it is duly packed and labeled.

2/ The label of any feed shall be written conspicuously either in the Amharic or English language.

17. Record Keeping

1/ Records shall be maintained and readily be available regarding the inputs, process and distribution of any feed.

2/ The record shall be kept in a manner that facilitates to trace suppliers of the inputs and consumers of the final product when any adverse effect of the product is identified.

18. Import and Export of Feed

1/ Any imported feed shall be accompanied with a certificate of quality authenticated by the concerned organ of the country of origin.

2/ Any feed to be exported shall be accompanied with a certificate of quality issued by the Authority.

19. Feed Trade

No person may engage in feed trade without obtaining a certificate of competence from the appropriate organ.
### PART FOUR
#### THE AUTHORITY AND INSPECTORS

20. **Powers and Duties of the Authority**

The Authority shall have the powers and duties to:

1. **prepare and submit to the competent organ standards for the safety, efficacy and quality of veterinary drugs and the safety and quality of feed and feed additives and, upon approval, follow up the implementation and observance of same;**

2. **set standards of competence for persons to engage in veterinary drug or feed trade; issue certificates of competence to those referred to in sub-article (2)(b) of Article 3 of this Proclamation; and renew, suspend or revoke certificates in accordance with this Proclamation and regulations and directives issued hereunder;**

3. **evaluate and register veterinary drugs and feed additives to be produced in the county or imported; and renew, suspend or revoke a registration in accordance with this Proclamation and regulations and directives issued hereunder;**

4. **prepare list of veterinary drugs and feed additives for the country, structure the drugs and feed additives in the list into different categories, revise the list whenever necessary;**

5. **formulate policies and legislations governing veterinary drugs and feed and, upon approval by the government, follow up their implementation;**

6. **promote and strength the veterinary drug and animal feed sector by monitoring domestic and foreign new scientific inventions and adapting them to the country’s specific conditions;**

7. **evaluate laboratory and clinical studies in order to ensure the safety, efficacy and quality of traditional veterinary drugs; and authorize the use of traditional veterinary drugs in the veterinary service;**
8/ serve as veterinary drug and feed information center; disseminate veterinary drug and feed information to professionals and the public; ensure the accuracy and relevance of information disseminated by others; and prohibit dissemination of ambiguous or erroneous information;

9/ authorize the conducting of clinical trial of veterinary drugs and monitor the process;

10/ monitor and regulate narcotic and psychotropic drugs used in veterinary practice, and report same to the Ethiopian Food, Medicine and Health Care Administration and Control Authority;

11/ organize quality control laboratories required to carry out its duties;

12/ provide training for the appropriate organs in handling and utilization of veterinary drugs and feed;

13/ register and regulate substances and mixtures used, in accordance with Article 2(2) of this Proclamation, for treatment of animal external parasites and controlling animal disease transmitting vectors; and report same to the organ empowered under Proclamation No. 674/2010; the detail implementation shall be in accordance with the regulation to be issued.

21. **Inspectors**

1/ The appropriate organs shall appoint veterinary drug and feed inspectors to ensure compliance of the provisions of this Proclamation and regulations and directives issued hereunder.

2/ Any inspector appointed in accordance with sub-article (1) of this Article shall have the powers and duties to:

a) 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;
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<th>Article</th>
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<td>b)</td>
<td>inspect records, documents, prescriptions, and computers related to veterinary drug and feed and take copies of such documents as may be necessary;</td>
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<td>c)</td>
<td>take samples of veterinary drugs, feeds or feed additives in accordance with the directives issued by the Authority;</td>
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<td>d)</td>
<td>subject to quality control veterinary drugs, feeds or feed additives suspected to be adulterated, spoiled, counterfeited, contaminated, or those suspected to be dangerous to users and order quarantine of such items until the results are known;</td>
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<td>e)</td>
<td>inspect the proper disposal of expired veterinary drugs, feed or feed additives or those determined to be unfit for use in accordance with this Proclamation.</td>
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3/ Any inspector conducting inspection activity shall have valid identification card issued by the appropriate organ and shall show it upon request.

PART FIVE

MISCELLANEOUS PROVISIONS

22. Disposal of Veterinary Drug and Feed and Cessation of Business

1/ Any person engaged in veterinary drug or feed trade shall keep deteriorated or expired drug or feed separately until its disposal.

2/ The disposal of veterinary drugs or feed shall be performed in accordance with directive issued by the Authority and with due care to avoid environmental pollution.

3/ When any person issued with a certificate of competence ceases to operate his trade, he shall deal with the stocks of drugs or feed and invoices, registers and prescriptions related to same in accordance with directive to be issued by the Authority.
### Advertisement and Provision of Information

1. The conditions of disseminating commercial advertisement of veterinary drug or feed through mass media or other means shall be determined by directive to be issued by the Authority.

2. Any mass media or advertising body shall be obliged to respect the directive issued by the Authority.

3. Persons engaged in veterinary drug and feed trades shall submit, periodically, information regarding their businesses in accordance with directive to be issued by the Authority.

4. The appropriate regional organs shall submit reports to the Authority on certificates of competence and professional licenses they have issued, suspended and revoked.

### Administrative Measures

1. The appropriate organ may suspend or revoke a certificate of competence or professional license where the holder thereof works in violation of this Proclamation or regulation or directive issued hereunder.

2. Where the appropriate organ ascertains that any veterinary drug or feed or feed additive is not safe for use, it may seize the veterinary drug or feed or feed additive and may order its disposal at the expense of its owner.

3. The appropriate organ may seal any veterinary drug or feed trade facility and take appropriate measure when it is operated by a person without having a certificate of competence.

### Complaints Handling

1. Any person who is aggrieved of the denial, suspension or revocation of a certificate of competence or professional license may lodge his complaint within 30 working days from the date of decision to the complaint handling body established by the appropriate organ.
2/ The body that has received a complaint in accordance with sub-article (1) of this Article shall render its decision within 30 working days.

3/ When the petitioner has not get decision with in the time specified under sub-article (2) of this Article or dissatisfied with the decision, he may submit the case to regular court.

26. Penalty

1/ Unless a higher penalty is prescribed in the Criminal Code any person who:

a) impedes the work of an inspector assigned pursuant to Article 21 of this Proclamation shall be punishable with simple imprisonment of not less than six months and with a fine not exceeding Birr 10,000;

b) transfers the certificate of competence or professional license issued to him to any person without the permission of the appropriate organ shall be punishable with simple imprisonment of not less than one year and not exceeding three years and with a fine not less than Birr 5,000 and not exceeding Birr 20,000.

2/ Any veterinary drug or feed manufacturer, importer or wholesaler who sales veterinary drugs or feed to a person without a certificate of competence shall be punishable with simple imprisonment of not less than two years and not exceeding five years and with a fine not less than Birr 10,000 and not exceeding Birr 20,000.

3/ Any person, with the exception of small holder farmers and pastoralists who sell their surplus, engages in veterinary drugs or feed trade without a certificate of competence shall be punishable with rigorous imprisonment of not less than five years and not exceeding seven years and with a fine not less than Birr 20,000 and not exceeding Birr 50,000.

4/ Any veterinary drug or feed wholesaler or retailer who purchases veterinary drugs or feed from a person who is not a holder of a certificate of competence shall be punishable with rigorous imprisonment of not less than two years and not exceeding 5 years and with a fine not less than Birr 10,000 and not exceeding Birr 20,000.
5/ Any person who counterfeits or adulterates veterinary drug or feed or supplies substandard or expired drugs or feed to the market shall be punishable with rigorous imprisonment of not less than 10 years and not exceeding 20 years and with a fine not less than Birr 20,000 and not exceeding Birr 50,000.

6/ Any person who fails to comply with other provisions of this Proclamation, or regulations or directives issued hereunder shall be punishable with simple imprisonment of not exceeding two years and with a fine not exceeding Birr 10,000.

7/ Any employee or official of the appropriate organ who, by taking bribes or through nepotism or other relationships, and in violation of this Proclamation or regulations or directives issued hereunder:

a) issues or renews or causes the issuance or renewal of a certificate of competence or professional license with respect to veterinary drug or feed trade; or

b) authorizes or causes the authorization of the use of veterinary drug, feed or feed additives without making adequate evaluation of its quality, safety and, where relevant, its efficacy; shall be punishable with rigorous imprisonment of not less than 10 years and not exceeding 15 years and with a fine not less than Birr 30,000 and not exceeding Birr 50,000.

8/ The penalty provided for under sub-article (7) of this Article shall also be applicable to a person who has given the bribe.

9/ If a person who participated in the commission of an offence provided for under sub-article (7) of this Article gives, before the case is submitted to a court of law, adequate information on the commission of the offence and the role of the major participants, the Ministry of Justice or the Federal Ethics and Anti-Corruption Commission may exempt the person from prosecution.

27. Inapplicable Laws

No law or practice may, in so far as it is inconsistent with the provisions of this Proclamation, be applicable with respect to matters covered by this Proclamation.
28. **Power to Issue Regulations and Directives**

1/ The Council of Ministers may issue regulations necessary for the implementation of this Proclamation.

2/ The Authority may issue directives necessary for the implementation of this Proclamation and regulations issued pursuant to sub-article (1) of this Article.

29. **Effective Date**

This Proclamation shall enter into force on the date of its publication in the Federal Negarit Gazette.

Done at Addis Ababa, this 19th day of January, 2012

GIRMA WOLDEGIORGIS

PRESIDENT OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA