A PROCLAMATION TO PROVIDE FOR FOOD, MEDICINE AND HEALTH CARE ADMINISTRATION AND CONTROL

WHEREAS, it is found necessary to protect the public health from unsafe, inefficacious and poor quality modern and traditional medicines;

WHEREAS, it is found necessary to protect the public from health risks emerging out of unsafe and poor quality food;

WHEREAS, it is found necessary to avert health problems due to substandard health institutions, incompetent and unethical health professionals, poor environmental health and communicable disease;

WHEREAS, it is found necessary to control and deter illicit production, trafficking and use of narcotic drugs, psychotropic substances, and precursor chemicals;

WHEREAS, in order to make the fragmented and poor quality administrative and regulatory system in the health sector efficient and effective, it is found necessary to establish a new and coordinated food, medicines and health care regulatory system;
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 “Food, Medicine and Health Care Administration and Control Proclamation No. 661/2009”.

2. Definitions

In this Proclamation, unless the context otherwise requires:

1/ "food" means any raw, semi-processed or processed substance for commercial purpose or to be served for the public in any way intended for human consumption that includes water and other drinks, chewing gum, supplementary food and any substance which has been used in the manufacture, preparation or treatment of food, but does not include tobacco and substances used only as medicines;

2/ "food trade" means production, preparation, irradiation, export, import, storage, distribution, transport, wholesale and retail of food and food raw materials for commercial purpose and includes the provision of food quality control laboratory service;

3/ “adulteration” means adding any foreign substance or ingredient to a food for commercial purpose or to be served for the public in any way or medicine other than its content or by substituting its content in whole or in part by such other substance or by storing or manufacturing it under unsanitary conditions whereby it may have been contaminated;

4/ “food additive” means any substance added to food to improve its taste, color, preservation or appearance and which is considered to become a component of food;
5/ “nutrition” means any food substance particularly enriched in protein, vitamin, mineral and any other similar contents that promote body health or protect health problems caused by malnutrition;

6/ “medicine” means any substance or mixture of substances used in the diagnosis, treatment, mitigation or prevention of a disease in human and includes narcotic drugs, psychotropic substances and precursor chemicals, traditional medicines, complementary or alternative medicine; poisons, blood and blood products, vaccine, radio active pharmaceuticals, cosmetics and sanitary items and medical instruments;

7/ “Pharmacopoeia” means a legal enforceable document issued or accepted by the government containing the particulars of medical drug preparation, physical aspects of medicinal and non-medicinal substances, preoperational aspect, content, intensity and standards and criteria’s to be fulfilled related to such particulars;

8/ “narcotic drug or psychotropic substance” means any drug subject to control according to the Narcotic Drugs or Psychotropic Substance Convention of the United Nations ratified by Ethiopia, and includes a drug that is categorized as narcotic or psychotropic drug by the executive organ;

9/ “precursor chemical” means any chemical, substance or mixture of substances subject to control according to the Convention of the United Nations ratified by Ethiopia to prevent illegal circulation of narcotic or psychotropic drugs, and include a substance that is categorized as precursor chemical by the executive organ;

10/ “tobacco product” means product entirely or partly made of the leaf tobacco as raw material which is manufactured to be used for smoking, sucking, chewing or snuffing;
11/ “poison” means any substance that may cause danger to human, animal, plant or environment even when taken in a small quantity;

12/ “sanitary item” means any preparation used in the maintenance of cleanliness of human, household, and includes pads, tampons, dentifrices, sweat-bands and detergents;

13/ “pesticide” means any substance or mixture of substances used to prevent, control or destroy pests to protect human, animal or plant health;

14/ “medical instrument” means any instrument or supply that may be used on the inner or outer part of the body for diagnosis or treatment of a disease in human, and includes various diagnostic, laboratory, surgery, dental medical instruments and suturing materials, syringes and needles;

15/ “traditional medicine” means any plant, animal or mineral product that can be used independently or in combination for the treatment of human or animal diseases;

16/ “cosmetic” means any preparation intended to be applied to the human body for cleansing, beautifying, promoting attractiveness or altering the appearance without affecting the body’s structure or functions. This includes products such as skin creams, lotions, perfumes, lipsticks, finger nail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, deodorant, medicated soaps and any ingredient intended for preparing these products;

17/ “medicine trade” means profit oriented production, repacking, import, export, wholesale or retail of medicines, and includes provision of quality control service, establishing and operating scientific offices and acting as a commission agent;
18/ “prescription” means any order for medicines written by a duly licensed medical practitioner issued to a patient in order to collect medicine from dispensing unit;

19/ “clinical trial” means testing medicines or medical procedure on human or animal subjects to prove its efficacy and safety;

20/ “radio active pharmaceutical” means a medicine which has one or more radionuclide substance used to examine, prevent or diagnose human or animal disease;

21/ “packing material” means any article that may be used for filling, inserting or wrapping or packing food or medicine, and includes immediate container and other materials for wrapping the product;

22/ “label” means any material which is printed or affixed to a packing material which provides the necessary information about a food or medicine, and includes an insert;

23/ “repacking” means packing of any processed or semi-processed food or medicine by a different manufacturing company in any other way;

24/ “certificate of competence” means a work license issued for a person to carry out food, medicine, health or health related services or trade in accordance with standards set;

25/ “counterfeiting” means using in any way, the packing material, identification or trademark, trade name or any special mark thereon of an authentic product of a manufacturer and presenting such falsely labeled and packed food or medicine as if it is manufactured by the genuine manufacturer or altering content and properties of food or medicine that cause health hazards to human;
26/ “inspector” means any professional authorized by the executive organ to perform inspection activities pursuant to this Proclamation;

27/ “suspected person” means a person who is judged by appropriate body as having been exposed to infection by a disease and is capable of communicating it;

28/ “waste” means liquid, solid or other waste generated from industries, agricultural institutions, schools, residential or commercial areas, health and research institutions, toilets or other similar institutions which can affect the health of human beings or animals;

29/ “poor environmental sanitation” means all factors in human physical environment which may cause a deleterious effect on the physical development, health and survival of human beings;

30/ “health professional” means a physician who is licensed by the executive organ to examine and diagnose human diseases and treat them by drug or surgical operations or any other health professional who is authorized to perform such activities;

31/ “medical practitioner” means a physician who is licensed by the executive organ to examine and diagnose human diseases and treat them by drug or surgical operations or any other health professional who is authorized to perform such activities;

32/ “medicinal professional” means a pharmacist, druggist, or pharmacy technician who is licensed by the appropriate organ;

33/ “traditional medication” means a medical service using plant, animal or mineral product or physical means out of indigenous and customary knowledge which is accepted by the society;
34/ "traditional practitioner" means a person who is licensed by the appropriate body to provide traditional medication;

35/ "complementary or alternative medicine" means a medication which is not indigenous traditional medication and associated with modern medicine and authorized to be rendered as complementary or alternative medicine;

36/ "complementary or alternative practitioner" means a person who is licensed by the executive organ to provide complementary or alternative medicine;

37/ "license" means a certificate issued for a health professional to provide medical or other health related services;

38/ "health institution" means any governmental, non-governmental or private institution that carry out promotive, preventive, curative and rehabilitative activities or medicine trade or services;

39/ "specialized health institution" means any specialized hospital, specialized center or institution that provides health service and training for physicians and professionals above that rank;

40/ "controllable health related institution" means any public place including schools, prisons, daycare centers, geriatric centers, orphanage centers, nurseries, market places, gyms, massage centers, recreation centers, barber and beauty salons;

41/ "occupational health care" means a science devoted to the application of scientific, technological and managerial principles to protect and control worker’ health by preventing or reducing risks that may occur within working areas or relating to occupation due to chemical, physical or biological agents;
3. Scope

1/ This Proclamation shall be applicable to regulatory activities in respect of food, medicine, environmental health, health professionals, health and controllable health related institutions in the country.

2/ Without prejudice to sub-article (1) of this Article, the application of this Proclamation at the federal level shall be in respect of:

42/ “bioequivalence center” means the center in which two types of medicine productions are ascertained by research as to their similarity of efficacy and safety;

43/ “executive organ” means a body to be established by regulations of the Council of Ministers to implement food, medicine and healthcare administration and control activities at the federal level;

44/ “appropriate organ” means, as the case may be, the executive organ or a state government organ authorized to implement food, medicine and controllable health related institution administration and control activities at a state level or other organ authorized by law;

45/ “Ministry” or “Minister” means the Ministry or Minister of Health, respectively;

46/ “state” means any state referred to under Article 47 of the Constitution of the Federal Democratic Republic of Ethiopia and includes Addis Ababa and Dire Dawa city administrations;

47/ “person” means any physical or juridical person;

48/ any expression in the masculine gender includes the feminine.
0/ setting standards in relation to food, medicine, environmental health, health professionals, health and controllable health related institutions;

b) licensing and regulating trans-regional food and medicine production, import, export, distribution, promotion and storage of food and medicine and quality control laboratory;

c) registering and licensing unsufficiency available health professionals;

d) registering and licensing health professionals coming from abroad to deliver health service;

e) licensing and regulating specialized health institutions;

f) monitoring and regulating trans-regional environmental health services;

g) undertaking quarantine service with concerned bodies at entry and exit ports; and

h) other regulatory activities with respect to trans-regional food, medicine, health and controllable health related services and institutions.

3/ Without prejudice to the generality of sub-article (2) of the Article, other regulatory activities which are not given to the executive organ under Article 4 of this Proclamation shall be carried out by states government regulatory bodies.
PART TWO

THE EXECUTIVE ORGAN AND INSPECTORS

4. Power and Duties of the Executive Organ

The executive organ shall have the powers and duties to:

1/ prepare and submit to appropriate organ health regulatory standards for safety and quality of food, safety, efficacy, quality and proper use of medicines, competence and practice of health professionals, hygiene and environmental health, competence of health and controllable health related institutions; and upon approval ensure the implementation and observance of the same;

2/ issue, renew, suspend and revoke certificate of competence for specialized health institutions, food and medicine processing plants, quality control laboratories, bioequivalence centers, importers, exporters, storages and distributors and trans-regional health service institutions;

3/ initiate policies and legislation to strengthen the quality of food and medicines and the competence of health professionals and health institutions; and submit the same for government approval;

4/ serve as medicine, food, health professionals and health and controllable health related institutions information center;

5/ identify ingredients that caused death or ill health due to medicine residue or adulteration of medicine and food and take appropriate measures by conducting investigation of sample ingredients;

6/ organize quality control laboratories as needed to carry out its duty;

7/ issue import and export permits for food, medicine, raw materials and packaging materials and undertake dead bodies control and give entry or exit permit;
8/ prepare pharmacopoeia for the country, structure the medicines included in the pharmacopoeia into different categories, revise the pharmacopoeia whenever necessary;

9/ evaluate and register medicines on the basis of registration requirements, and renew, suspend and revoke such registrations;

10/ undertake and coordinate post marketing surveillance in order to ensure the safety and quality of food and safety, efficacy and quality of medicines that are put into use and take appropriate measures;

11/ authorize conducting clinical trial, monitor the process as to its conduct in accordance with good medical procedure, evaluate the results and authorize the use of the result in such a way that it benefits the public; suspend or stop the clinical trial where necessary;

12/ monitor and control manufacture, import, export, distribution, prescribing, dispensing, use, recording and reporting of narcotic drugs, psychotropic substance and precursor chemicals, prevent their abuse and report the same to the International Narcotic Control Board;

13/ regulate the content, manufacture, import, export, distribution, sales, use, packaging and labeling, advertisement and promotion, and disposal of tobacco products;

14/ undertake inspection on planes entering the country to ensure the protection of health and control of communicable diseases and undertake fumigation and give certificate for planes departing the country;

15/ undertake control of communicable diseases at entry and exit port on international travelers and, where necessary, prohibit them from entry or exit or subject them to be quarantined; ensure that necessary preventive and control measures are taken in the case of outbreak of trans-regional communicable diseases;
16/ issue, renew, suspend and revoke license to unsufficiently available health professionals, complementary and alternative medicine practitioners and health professionals coming privately or in group from abroad to deliver health service;

17/ ensure proper disposal of expired medicine and foods and their raw materials;

18/ ensure that handling and disposal of trans-regional solid and liquid wastes from different institutions are not harmful to public health;

19/ control illegal food, medicine and health services and take appropriate measures;

20/ ensure that the quality of trans-regional water supply for the public is up to the standard;

21/ ensure the availability of necessary hygienic requirements in controllable health related institutions under the federal government;

22/ provide the necessary support to state regulatory bodies on food, medicine and healthcare with a view to harmonizing federal and regional regulatory system.

5. Inspectors

1/ The executive organ shall appoint inspectors to implement the provisions of this Proclamation and other laws and directives related with food, medicine and healthcare administration and control.

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

a) enter and inspect, during working hours, the establishments of food and medicine importers, exporters, producers, distributors and transporters and health and controllable health related institutions;
b) inspect foods, medicines, vaccination certificates, deed bodies, air crafts and other health related activities at ports of entry and exist;

c) enter and inspect any premises or building which he has sufficient reason to believe that there exists a situation endangering public health;

d) where it is necessary for conducting investigation or gathering evidence, take samples, measurements and photographs of foods and medicines and retain a photocopy of records;

e) subject to quality control food and medicines that are adulterated, spoiled, counterfeit, contaminated or those suspected to be dangerous to the public and to order the quarantine of such items until the laboratory results are known;

f) where he has sufficient reason to believe that any article or material found in any premise or building which is under investigation is likely to cause damage to health, order that it shall be kept separately until the investigation results are known;

g) inspect the proper disposal of foods and medicines when they expire or when they are deemed to be unfit for use in accordance with this Proclamation.

PART THREE

FOOD SAFETY AND QUALITY ADMINISTRATION AND CONTROL

6. Registration and License

1/ Any food may not be manufactured, imported, exported, stored, distributed, transported or made available for sale or use to the public without permit of the appropriate organ.
2/ Any food production institution shall not change the type and production process of the food without obtaining a permit from. And having it registered with, the executive organ.

7. Food Safety and Quality Control

1/ No food or its raw material, additive or packaging material shall be be put into use unless it complies with the international and national safety and quality standards.

2/ Any food shall be preserved in accordance with the standards set or adopted by the appropriate organ.

3/ Any person may not operate a laboratory established for food quality control unless it is receives certificate of competence from the executive organ.

4/ Any person may not operate a food catering service without obtaining a certificate of competence from the appropriate organ.

5/ A certificate of competence issued in accordance with sub-article (4) of this Article shall be renewed every year.

6/ It is prohibited for any institution that engages in food production, processing, storing, distribution and transportation to hire an employee having contact with the product and who is infected with communicable disease.

8. Packaging and Labeling

1/ Any producer, importer, distributor or retailer of packed food shall not supply it to the market or distribute it otherwise unless it is duly packed and labeled.

2/ The label of any packed food shall be written either in Amharic or English language.
9. Nutrition

1/ No person may involve in the production of nutrition unless it fulfills the standards set by the appropriate organ.

2/ No person may disclose the nutritious content in the food it produces without obtaining approval from the executive organ.

3/ The type and content of nutrition, usage guide and shelf-life of nutritionally produced food shall be stated in an unfading and clearly mark on its package.

4/ Any person who produces or distributes salt for human consumption shall ensure that it meets the standard requirement of iodine content.

10. Food Import and Export

1/ Any imported food shall be accompanied by a certificate of quality and safety authenticated by the concerned government organ of the exporting country.

2/ The executive organ may issue safety certificate for export food that needs the same.

11. Food Irradiation

Radiation treatment of food shall be carried out upon ascertaining by the executive organ that it is designed to meet the requirements of safety and good hygienic practice of food processing.

12. Water Quality Control

1/ It is prohibited to supply water for public consumption from springs, wells or through pipes unless its quality is verified by the appropriate organ.

2/ It is prohibited to import or produce and distribute bottled mineral or plain water for public consumption unless its quality is verified by the executive organ.
PART FOUR

ADMINISTRATION AND CONTROL OF MEDICINE

13. Registration of Medicines

1/ No medicine shall be produced locally or imported and put in use unless it is duly registered by the executive organ after being tested for its safety, efficacy and quality.

2/ Notwithstanding the provisions of sub-article (1) of this Article, the executive organ may, in unforeseen circumstances, give permits for the importation and use of medicines not registered.

3/ The certificate of registration of a medicine shall be renewed every four years where the medicine continues to meet the requirements of registration.

4/ Unforeseen circumstances mentioned under sub-article (2) of this Article shall be determined by Regulations to be issued pursuant to this proclamation.

14. Quality Standards and Appropriate Use of Medicine

1/ Any medicine or raw material or packaging material of a medicine shall meet quality standards and requirements prescribed in the pharmacopoeia issued or adopted by the appropriate organ or, where it is not included in such pharmacopoeia, those standards and requirements prescribed by manufacturing companies and accorded with international or the appropriate organ’s acceptance.

2/ Where any medicine lacks the expected use of safety, efficacy and quality for which its permit is granted, or its risk outweighs its benefit, its use shall be banned and its registration shall be revoked.
3/ Any medicine shall be available for use in accordance with the standard and working directives to be issued by the executive organ to ensure the appropriate use of medicine.

15. Clinical Trial

1/ A clinical trial shall, without prejudice to the provisions of sub-article (2) of this Article, be conducted on a human being only when it is authorized by the executive organ.

2/ The clinical trial on a human being shall be conducted where the person gives consent in writing.

3/ Notwithstanding the provisions of sub-article (1) and (2) of this Article, a clinical trial may not be conducted on nursing and pregnant women, persons under the age of 18, prisoners and insane persons.

4/ Without prejudice to the provisions of sub-article (3) of this Article, a clinical trial may not be conducted on nursing and pregnant women, persons under the age of 18, prisoners, insane persons and persons dependant on the professional or the institution conducting the clinical trial except where there is a necessary ground and a special permission from the executive organ in accordance with the regulation to be issued pursuant to this Proclamation.

5/ It shall be the duty of the person who is authorized to conduct the clinical trial to report to the executive organ the result of the clinical trial.

6/ A person who conducts the clinical trial shall pay compensation for the person subjected to the trial the actual damage the trial has caused to him.

16. Packaging and Labeling

1/ Any producer, importer, distributor, retailer or health institution of medicine shall not supply it to the market or distribute it otherwise unless it is duly packed and labeled.
2/ The label of any medicine shall be written either in the Amharic or English language.

17. Poisons, Radio active Pharmaceuticals and Pesticides

1/ No person may, without obtaining a certificate of competence from the appropriate organ, produces, imports, exports, distributes or sales poisons or radio active pharmaceuticals.

2/ Any person issued with a certificate of competence pursuant to sub-article (1) of this Article shall keep records and submit reports to the appropriate organ on manufactured, imported, distributed or sold poisons or radio active pharmaceuticals.

3/ Packaging, transportation, storage and distribution of pesticides, poisons and radio active pharmaceuticals shall be in such a manner that minimizes danger to the life of human being, animals and the environment.

4/ The executive organ shall jointly work with the appropriate organ to ensure that the production, transportation, storage, usage and disposal of pesticides do not cause any health hazard.

PART FIVE

NARCOTIC DRUGS, PSYCHOTROPIC SUBSTANCES AND PRECURSOR CHEMICALS

18. Requirement of Special Permit

1/ Any person shall, to import, export, manufacture, distribute, store or possess narcotic drugs, psychotropic substances or precursor chemicals, be required to have a special permit issued by the executive organ.

2/ A special permit shall be issued pursuant to sub-article (1) of this Article only to a person who has obtained a certificate of competence with respect to the import, export, manufacturing, distribution or storage of medicine or the provision of health service.
3/ A special permit issued pursuant to sub-article (1) and (2) of this Article for the import or export of narcotic drugs, psychotropic substances or precursor chemicals shall apply for a specific consignment and shall be valid for 90 days from the date of its issuance.

4/ It shall be prohibited to import or export narcotic drugs, psychotropic substances or precursor chemicals:

a) through post office or by ship; or

b) as packed with other medicines or goods.

19. Prescriptions Procedure

1/ Only a medical practitioner who has a special permit and in the health institution where he is authorized to work shall prescribe narcotic drugs and psychotropic substances.

2/ No medical practitioner may prescribe narcotic drugs and psychotropic substances for himself.

3/ The prescription of a narcotic drug or psychotropic substance shall be in a special prescription paper.

20. Storage and Reporting

1/ Narcotic drugs and psychotropic substances and invoices, registers, and prescriptions shall be stored in a lockable metal cupboard or in a special room the key of which shall at all times remain in the hands of the authorized medical practitioner.

2/ Any person issued with a special permit shall keep records and submit reports regarding narcotic drugs, psychotropic substances or precursor chemicals in accordance with directives issued by the executive organ.
21. Disposal and Cessation of Business

1/ Any concerned person shall keep damaged, expired or seized narcotic drugs, psychotropic substances or precursor chemicals in a separate place and shall dispose them in accordance with directives issued by the executive organ.

2/ Any person issued with a special permit and who ceases to operate his business shall deal with the stocks of narcotic drugs, psychotropic substances or precursor chemicals and invoices, registers and prescriptions related to same in accordance with directives issued by the executive organ.

22. Control of Tobacco

1/ Any person shall be required to have a special permit to import, export or whole sale tobacco products.

2/ Content, manufacture, import, export, distribution, sales, use, advertisement and promotion, packaging and labeling and disposal of tobacco products shall be in conformity with regulations issued under this Proclamation.

PART SIX
HYGINE, ENVIRONMENTAL HEALTH AND CONTROL OF COMMUNICABLE DISEASES

23. Occupational Health and Safety

1/ Any employer shall ensure the availability of occupational health services to his employees.

2/ The executive organ shall issue appropriate directive on occupational health and use of machinery.
24. Dangerous Chemicals

1/ It shall be prohibited to transport or store chemicals with foods or in a manner which can cause pollution to the environment and endangering public health.

2/ Any person who produces, transports or stores dangerous chemicals shall fulfill the requirements set by the executive organ in order not to affect the environment and public health.

25. Constructions

Any person constructing a building for any service shall fulfill the public health requirements set by the executive organ.

26. Health Control at Entrance and Exit Ports

1/ Any passenger coming to or leaving Ethiopia shall be obliged to take vaccination required for international passengers in accordance with international public health requirements adopted by Ethiopia and to show, at ports of entry and exit, his certificate whenever requested by the relevant health authority and, where suspected of any communicable disease, to cooperate for medical examination.

2/ Any person without having an appropriate health certificate or coming from an epidemic area may not be allowed to enter Ethiopia.

3/ The appropriate officer at any port of entry or exit shall have the duty to report any suspected passenger of any communicable disease to the nearest health office.

4/ It shall be prohibited to transport animals together with passengers without valid health certificate and protection.
27. Communicable Diseases

1/ Any health professional who happens to know the existence of communicable disease in his vicinity shall have the duty to report immediately to the nearest health service institution. The institution which has received such report shall take the necessary measures and report same to public health emergency control body.

2/ The appropriate health professional shall quarantine a person infected or suspected of epidemic disease for a limited period of time.

3/ Any person suspected of epidemic disease shall cooperate for medical examination, treatment or vaccination.

4/ Parents or guardians shall have the duty to cause the vaccination of children for the protection of communicable disease.

28. Zoonosis

1/ Any person who is infected or suspected of zoonosis or has come from the area where such disease occurs shall have the duty to cooperate for any control activity.

2/ Every health institution shall have the duty to render the appropriate service for zoonosis in accordance with its level of competence and immediately refer to the appropriate health institution where it is not capable of providing the service.

3/ Every health institution shall observe zoonosis prevention and control directives to be issued from time to time.
29. Disposal and Transport of Dead Body

1/ It is prohibited to allow dead body or human remains either to enter or leave the country without the approval of the executive organ.

2/ Any person shall observe the requirements set by the executive organ to bury, exhume or transport dead body or human remains.

30. Waste Handling and Disposal

1/ No person shall collect or dispose solid, liquid or other wastes in a manner contaminating the environment and harmful to health.

2/ Any wastes generated from health or research institutions shall be handled with special care and their disposal procedures shall meet the standards set by the executive organ.

3/ It is prohibited to discharge untreated waste generated from septic tanks, seepage pits, and industries into the environment, water bodies or water convergences.

31. Availability of Toilet facilities

1/ Any institution providing public service shall have the obligation to organize clean and adequate toilet facilities and keep it open to its customers.

2/ Any city or rural administration shall be responsible to provide public toilet and ensure its cleanliness.

32. Control of Bathing Places and Pools

1/ Any person providing a public bathing place, swimming pool, natural steam bath or hot spas shall fulfill the requirements set by the executive organ.
33. Requirement of Professional License

1/ No person shall practice as a health professional without having obtained a professional practice license issued by the appropriate organ.

2/ Professional practice license given to any health professionals shall be renewed every five years upon ethical and competence evaluation.

3/ A health professional whose license has been suspended or revoked shall be prohibited to practice his profession.

4/ The appropriate organ shall notify to the public the list of health professionals whose licenses have been suspended and revoked.

34. Standards of Care and Scope of Practice

Any health professional shall practice his profession in accordance with the standards of health care and scope of professional practice set by the executive organ.

35. Code of Conduct

1/ Any health professional shall perform his professional duties in accordance with the relevant code of ethics.

2/ The code of conduct for health professionals shall be determined by regulations to be issued pursuant to this Proclamation.

36. Duty to Report

1/ Any health professional or other person who is aware of the existence of professional mal-practice shall report the same to the appropriate regulatory organ.
2/ Any health professional who is aware of or suspects the existence of communicable diseases identified as reportable diseases by public health emergency control organ shall immediately report same to the public health emergency control organ.

37. Information of Patients and Obligations of Health Institutions

1/ Any health professional shall fully record personal health information generated during each encounter with a patient within a health institution.

2/ Any health institution shall have the duty to ensure that the records of personal health information referred to in sub-article (1) of this Article are kept and maintained properly.

3/ Any personal health information of a patient shall be confidential unless it is requested for a legitimate purpose authorized by law.

4/ Without prejudice to sub-article (3) of this Article, patients’ health information generated and maintained in accordance with sub-articles (1) and (2) shall be aggregated and reported to the appropriate organ on time.

38. Emergency Treatment and Referral

1/ Any health professional shall have the duty to render emergency medical treatment within the scope of his professional practice.

2/ Where a health professional is not capable of providing the necessary emergency medical treatment in accordance with the health institution’s standard, he shall immediately refer the patient, in accordance with the referral system, to an appropriate health institution which is capable of providing the necessary treatment.
39. Prescribing and Dispensing of Medicines

1/ Medicine shall only be prescribed by a medical practitioner who is licensed by the appropriate organ.

2/ Any medical practitioner shall prescribe medicine following prescription procedures and on a standard prescription paper.

3/ Medicines shall be dispensed by medical professionals.

4/ Without prejudice to sub-article (3) of this Article, the executive organ, in accordance with the directive to be issued, may permit as to the dispensation of medicines by health extension professionals and, in compelling circumstances, by other health professionals.

5/ Any licensed professional dispenser of medicine shall dispense medicines with care by rendering enough information and understanding based upon dispensing procedures.

6/ Any professional dispenser of medicine may not dispense medicines without prescription issued in accordance with medicines prescribing procedures, except medicines dispensed without prescription.

40. Interns or Residents

1/ Any health institution which let interns or residents to practice the respective stream of their studies, the institution and the school shall be duty bond to follow up their training and practice.

2/ Notwithstanding sub-article (1) of this Article, any intern or resident may be held responsible for any injury he causes to a patient.
PART EIGHT
HEALTH AND CONTROLLABLE HEALTH RELATED INSTITUTIONS

41. Requirement of Certificate of Competence

1/ A person requiring to establish health institution or medicine trade of service or to undertake change within the institution shall obtain certificate of competence from the appropriate organ.

2/ A certificate of competence issued in accordance with sub-article (1) of this Article shall be renewed every year.

42. Standard of Health Institutions

The executive organ shall determine the categories and standards of services to be provided by health institutions.

43. Cessation of Business

Any health institution or medicine trade establishment which ceases to operate its business shall deal with the stocks of medicines and invoices, registers and prescriptions related to same in accordance with directives issued by the executive organ.

44. Controllable Health Related Institutions

Any controllable health related institution shall meet the standards of hygienic requirements set by the executive organ.

PART NINE
TRADITIONAL AND COMPLEMENTARY OR ALTERNATIVE MEDICINE

45. Registration

Any locally produced or imported traditional, complementary or alternative medicine may not be put into use unless evaluated and registered by the executive organ.
46. **License Requisite**

1/ No person shall practice as a traditional or complementary or alternative medicine practitioner without having obtained a practice license issued by the appropriate organ.

2/ A traditional, complementary or alternative medicine practitioner’s license shall be renewed every five years upon ethical and competence evaluation of the licensee.

3/ A traditional, complementary or alternative medicine practitioner whose license has been suspended or revoked shall be prohibited to practice his profession.

47. **Traditional, Complementary or Alternative Medicine Service Premises**

1/ Any person may not render traditional, complementary or alternative medicine service out of the premises approved by the appropriate organ.

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

3/ A certificate of competence issued pursuant to sub-article (2) of this Article shall be renewed every year.

48. **Administrative measures**

1/ A certificate of competence or license issued by the appropriate organ may be suspended or revoked where the holder thereof works in violation of this Proclamation or regulations or directives issued hereunder.
2/ Where the appropriate organ ascertains that any medicine or food is not safe for use, it may seize the medicine or food and dispose or send it back to the country of origin at the expense of its owner or possessor.

3/ The appropriate organ shall close any health institution or medicine trade establishment operated without having a certificate of competence and take appropriate actions.

49. Complaints Handling

1/ Any person who is aggrieved of the denial, suspension or revocation of a certificate of competence or license may lodge his compliant within 30 days from the date of decision to the grievance hearing body established by the appropriate organ.

2/ The body received a complaint in accordance with sub-article (1) of this Article shall render its decision within 30 days.

PART ELEVEN
MISCELLANEOUS PROVISIONS

50. Commercial Advertisement

1/ Commercial advertisement of food, medicine or health service through mass media or other means shall be determined by directive issued by the executive organ.

2/ Any mass media or advertising organ shall be obliged to respect the directive issued.

3/ The executive organ shall ensure the implementation of the food, medicine or health service commercial advertisement directive.
51. Submission of Information

1/ Food, medicine, health and controllable health related service rendering institutions shall submit periodical information regarding their services in accordance with directives of the appropriate organ.

2/ State regulatory or delegated organs shall submit report to the executive organ on license/certificate of competence and professional license they have issued, suspended and revoked.

52. Duty to Cooperate

The concerned federal and regional bodies shall have the duty to cooperate with the executive organ with a view to facilitating the effectively discharging its duties under this Proclamation.

53. Penalty

1/ Unless a higher penalty is provided under the Criminal Code:

a) Any licensed person who:

(1) impedes the work of inspector assigned pursuant to sub-article (2) (a) of Article 5 of this Proclamation shall be punishable with imprisonment for not less than one year and not exceeding five years or with a fine not less than Birr 10,000 and not exceeding Birr 50,000 or with both;

(2) transfers the certificate of competence or license issued to him to any person by way of any means without the permission of the executive organ shall be punishable with imprisonment of not less than two years and not exceeding five years and a fine of not less than Birr 50,000 and not exceeding Birr 100,000;
b) Any licensed medicine manufacturer, importer, exporter or wholesaler who sales medicine to a person without a certificate of competence or license shall be punishable with imprisonment of not less than five years and not exceeding seven years and with a fine of not less than Birr 50,000 and not exceeding Birr 100,000;

c) Any person who trades medicines without a certificate of competence shall be punishable with imprisonment for not less than five years and not exceeding seven years and with a fine of not less than Birr 50,000 and not exceeding Birr 100,000;

d) Any person who conduct clinical trail in violation of Article 15 shall be punishable with imprisonment of not less five years and not exceeding seven years and with a fine of not less than Birr 50,000 and not exceeding birr 100,000;

e) Any person who advertises in violation of Article 22 or 50 of this Proclamation shall be punishable with imprisonment of not less than six months and not exceeding one year or with a fine of not less than Birr 5,000 and not exceeding birr 10,000 or with both;

f) Any person who advertises by way of any means to encourage the abuse of narcotic drugs or psychotropic substances or causes or allows such advertising or causes the illegal production of narcotic drugs or psychotropic substances through the inappropriate use of precursor chemicals shall be punishable with imprisonment of not less than seven years and not exceeding fifteen years and with a fine of not less than Birr 30,000 and not exceeding Birr 50,000;

g) Any person who violates the provisions of Article 7 (1) or (2) about food safety and quality or Article 8 about food packaging and labeling of this Proclamation shall be punishable with imprisonment of not less than two years and not exceeding five years and with a fine of not less than Birr 20,000 and not exceeding Birr 50,000;
h) Any person who violates Article 6 about registration and licensing of food, Article 9 about standards for nutrition and labeling or Article 11 about food irradiation of this Proclamation shall be punishable with imprisonment of not less than one year and not exceeding three years or with a fine of not less Birr 5,000 and not exceeding Birr 10,000 or with both;

i) Any person who violates:

1/ Article 12 about water quality control of this Proclamation shall be punishable with imprisonment of not less than three years or with a fine of not less than Birr 20,000 and not exceeding Birr 40,000 or with both;

2/ Article 24 about dangerous chemicals of this Proclamation shall be punishable with imprisonment of not less than five years or with a fine of not less than Birr 50,000 and not exceeding Birr 100,000 or with both;

j) Any person who does not provide occupational health services under Article 23 (1) of this Proclamation shall be punishable with imprisonment of not less than three years or with a fine of not less than Birr 20,000 and not exceeding Birr 40,000 or with both;

k) Any person who violates construction standards under Article 25 of this Proclamation shall be punishable with imprisonment of not less than three months and not exceeding one year or with a fine of not less than Birr 5,000 and not exceeding Birr 10,000 or with both;

l) Any person who violates Article 31 about organizing toilet facilities or Article 32 about bathing places and pools of this Proclamation shall be punishable with a fine of not less than Birr 3,000 and not exceeding Birr 5,000;
m) Any health professional who violates requirements of professional license under Article 33 or standards of care and scope of practice under Article 34 of this Proclamation shall be punishable with imprisonment of not less than two years and not exceeding five years;

n) Any person who violates:

1/ the duty to report communicable diseases under sub-article (1) or the duty to quarantine a person infected or suspected of epidemic disease under sub-article (2) of Article 27 of this Proclamation shall be punishable with imprisonment of not exceeding six months or fine of not exceeding Birr 3,000 or with both;

2/ the duty to report under Article 36 of this Proclamation shall be punishable with imprisonment of not less than six months and not exceeding 2 years or with a fine of not exceeding Birr 5,000 and not exceeding birr 10,000 or with both;

3/ the duty with respect to patients’ information and of health institutions under Article 37 of the Proclamation shall be punishable with imprisonment of not exceeding one year or fine of not exceeding Birr 10,000 or with both;

o) Any person who violates Article 45 about traditional, complementary or alternative medicine registration, Article 46 about traditional, complementary or alternative medicine practitioner licensing or Article 47 about traditional, complementary or alternative medicine service premises of the Proclamation shall be punishable with imprisonment of not less than one year and with a fine of not less than Birr 5,000 and not exceeding birr 10,000.

2/ Any employee or official of the appropriate organ who, by taking bribes or through nepotism or other illegal 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 medicine, food or health or controllable health related institution services; or

b) authorizes or causes the authorization of the use of food or medicine or raw materials without making adequate evaluation, where relevant, of their quality, safety and efficacy;

shall, unless a higher penalty is provided under the criminal code, be punishable with imprisonment of not less than seven years and not exceeding fifteen years and with a fine not less than Birr 30,000 and not exceeding birr 50,000.

3/ The penalty provided for under sub-article (2) of this Article shall also be applicable to a person who has given the bribe.

4/ If a person who participated in the commission of an offence provided for under sub-article (2) of this Article gives, before the case is submitted to a court, adequate information on the commission of the offense and the role of the major participants, the Ministry of Justice may exempt the person from prosecution pursuant to this Proclamation.

54. Repeal and Inapplicable Laws

1/ The following laws are hereby repealed:

a) the Drug Administration and Control Proclamation No. 176/1999; and

b) the Public Health Proclamation No. 200/2000.

2/ No law, regulation, directive or practice shall, in so far as it is inconsistent with this Proclamation, be applicable with respect to matters provided for by this Proclamation.

55. Power to Issue Regulations and Directives

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

This Proclamation shall enter into force up on the date of publication in the Federal Negarit Gazeta.

Done at Addis Ababa, this 13th day of January, 2010

GIRMA WOLDEGIORGIS

PRESIDENT OF THE FEDERAL DEMOCRATIC REPUBLIC OF ETHIOPIA