WHEREAS, it is necessary to prevent and control the public’s health from health hazards caused by unsafe food;

WHEREAS, it is necessary to prevent and control the public’s health from unsafe, inefficacious and poor quality medicine, and unsafe and ineffective medical device;

WHEREAS, it is necessary to prevent and control the illegal distribution and use of narcotic drugs, psychotropic substances, and precursor chemicals;

WHEREAS, it is necessary to install a regulatory scheme compatible with the country’s expanding industry and manufacturing sector;

WHEREAS, it is necessary to prevent and control the public’s health from the devastating health, social, and economic consequences of tobacco product;
WHEREAS, it is necessary to adopt a national legal framework that enables to establish a coordinated food, medicine, medical device, cosmetics, and tobacco products regulatory system; and

NOW, THEREFORE, in accordance with Article 55(1) of the Constitution of the Federal Democratic Republic of Ethiopia, it is hereby proclaimed as follow:

PART ONE
GENERAL

1. Short Title
This proclamation may be cited as the "Food and Medicine Administration Proclamation No.1112/2019"

2. Definitions
In this Proclamation, unless the context otherwise requires:

1/ "food" means any substance, whether processed or semi-processed, which is intended for human consumption, and includes plants, and plant and animal products placed on the market or offered for use by the public; salt, water, alcohol or other drink, and any substance which has been used in the manufacture or treatment of food but does not include medicine, cosmetic, and tobacco products;

2/ "food trade establishment" means an institution involved in the manufacture, export, import, wholesale, retail sale, or repacking of any food for profit;

3/ "food establishment" mean any food trade establishment and other humanitarian and service provision institutions that provide food for public consumption on a regular and non-profit basis;
4/ "food safety" means the conditions and practices that preserved food is fit for human consumption during manufacturing, handling, storage, or transport;

5/ "irradiation" means a deliberate exposure of food to ionizing radiation;

6/ "infant formula" means industrially formulated food to satisfy the normal nutritional requirements of infants up to six months of age;

7/ "follow-up formula" means a food product of animal or vegetable origin and industrially formulated in accordance with the appropriate standard for feeding infants and young children from six months up to three years of age;

8/ "food supplement" means a concentrated source of vitamin, mineral or other substance with nutritional or physiological effect, alone or in combination prepared in a dosage form and intended to supplement the normal diet;

9/ "medicine" means any substance or mixture of substance used in the diagnosis, treatment, mitigation or prevention of human disease, disorder, abnormal physical or mental state, or the symptoms thereof; used in restoring, correcting or beneficial modification of organic or mental functions in human; or articles other than food, intended to affect the structure or any function of the body of human and it includes articles intended for use as a component of any of the above specified articles;
10/ “pharmacy professional” means a pharmacist, druggist, or pharmacy technician licensed by the appropriate health professional regulatory organ;

11/ “narcotic drugs” means a medicine subject to control in accordance with the Convention issued by United Nations and ratified by Ethiopia and include a drug that is categorized as narcotic drug by the executive organ;

12/ “psychotropic substance” means any substance subject to control in accordance with the Convention issued by United Nations and ratified by Ethiopia and include a drug that is categorized as psychotropic substance by the executive organ;

13/ “radiopharmaceuticals” means a medicine which has one or more radionuclide substance used in the diagnosis and treatment of human disease and includes non radioactive reagent kit used for a preparation of medicine and radionuclide generator;

14/ “precursor chemical” means any substance or mixture of substances subject to control in accordance with the Convention issued by the United Nations and ratified by Ethiopia and include a substance that is categorized as precursor chemical by the executive organ;

15/ “prescription” means a paper or electronic order for medicine that meets requirements set by the executive organ, and written and signed by a duly licensed medical professional;
16/ "raw material" means the basic material from which a regulated product is made;

17/ "blood product" means a product prepared from human blood or liquid blood for medical purposes;

18/ "blood" means include human blood, blood collected for transfusion or processed blood;

19/ "counterfeiting" means a deliberate or fraudulent mislabeling of a product in respect of its identity and/or source including the packing material, identification or trademark, trade name, any special mark thereon of an authentic product and presenting such falsely labeled product as if it is manufactured by the genuine manufacturer;

20/ "adulteration" means adding any foreign substance or ingredient or substituting the content of the product in whole or in part by such other substance so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is;

21/ "pharmacopela" means a document accepted by the appropriate organ containing the particulars of medicine preparation, physical aspects of medicine and non-medicinal substances, preperation aspect, content, intensity and standards and criteria's to be fulfilled related to such particulars;
22/ “medical device” means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related articles, and their accessories, which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, and intended by the manufacturer to be used, alone or in combination, for medical purpose and includes device intended for related medical use and control of contraception;

23/ “in vitro medical device” means a device, whether used alone or in combination, intended by the manufacturer for the in vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes, and includes reagents, calibrators, control materials, specimen receptacles, software or related other articles;

24/ “refurbished medical device” means a medical device whose service year is yet to expire or has already expired and undergone the appropriate renovation and effectiveness testing for use in medical purpose;

25/ “remanufactured medical device” means a medical device which is taken back to a manufacturer after use by a health institution and rebuilt based on the effectiveness and safety specification of the original manufacturer;
26/ "clinical trial" means any systematic study on medicine or medical devices in volunteer human subjects in order to discover or verify the effects of, and/or identify any adverse reaction to the products, and or to study its absorption, distribution, metabolism, and excretion with the object of ascertaining their efficacy and safety;

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

28/ "public health pesticide" means any substance or mixture of substances used to prevent, control or destroy pests to protect human health and includes pesticide-treated mosquito net;

29/ "cosmetic" means any article intended to be used by means of rubbing, pouring, steaming, sprinkling, spraying on or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness or altering the appearance and, any article intended for use as component of a cosmetic but such articles excludes laundry soaps, articles intended for the diagnosis, treatment, mitigation or prevention of human disease, and products intended to affect the anatomy or of a physiological process of a human;
36/ "other related cigarette resembling technology product" includes any tobacco product that is consumed by creating an aerosol or vapour via a process of heating tobacco without full combustion and includes any device and associated parts intended for use in consumption of the product, whether or not sold separately from the product;

37/ "characterizing flavor" means a taste or smell, other than one of tobacco, resulting from a natural or artificial additive or a combination of additives, including, but not limited to, fruit, chocolate, vanilla, honey, candy, cocoa, menthol, alcohol, spice or herbs which is noticeable before or during the consumption of the tobacco product;

38/ "shisha" means includes tobacco products that may be flavored or non-flavored that are consumed using a single or multi-stemmed smoking instrument that contains water or other liquid through which the smoke passes before reaching the smoker and whose syrup tobacco content includes molasses, honey, vegetable glycerol and fruit flavors;

39/ "primary packing" means the covering, wrapper, or container that has direct contact with the product intended for retail sale;

40/ "barcode" means a machine-readable code in the form of numbers and a pattern of parallel lines printed on and identifying a product for the purpose of monitoring by the manufacturer or executive organ;
41/ "alcohol" means any drink with 0.5% or more alcohol volume;

42/ "generic name" means a chemical term by which a medicine is addressed without referring to its brand name;

43/ "means of advertisement dissemination" means includes the mass media, outdoor advertisement, telecom, postal, internet website and fax services, cinema, film, video and any other related means of advertisement dissemination;

44/ "regulated product" means any product administered in accordance with this proclamation and includes food, medicine, medical device, cosmetic, and tobacco products;

45/ "medical professional" means a physician or other health professional who is authorized by the appropriate organ to examine and diagnose human diseases and treat them by drug, surgical operations or other related medical means;

46/ "packing" means any article that may be used for filling, inserting or wrapping or packing regulated products and includes the immediate container and other wrapping materials;

47/ "label" means all labels and other written, printed, or graphic material that is affixed to a regulated product or any of its container or wrapper and includes insert;
48/ "repacking" means packing of any processed or semi-processed regulated products by a different manufacturer in any other way;

49/ "inspector " means any professional authorized by the executive organ or regional health regulator to perform inspection activities pursuant to this Proclamation;

50/ "institution registration" means a recognition granted to regulated institution in accordance with set requirements;

51/ "product registration" means a recognition granted to regulated product in accordance with set requirements;

52/ "quality control system" means a procedure intended to ensure that a regulated product meets quality and safety requirements;

53/ "institution" means any establishment involved in the manufacture, export, import, wholesale, retail, or repacking of regulated products;

54/ "manufacture" means all operations involved in transforming raw materials into regulated products under this proclamation including in the preparation, processing, compounding, formulating, filling, packing, packaging, and repackaging;

55/ "food additive" means any substance prepared in accordance with applicable requirements and added to food in order to give flavor, impart color, preserve, and enhance its appearance or other related functional purposes;
56/ "certificate of competence" means a certificate issued for a person to carry out the manufacture, import, distribution, wholesale, retail or re-sale of regulated products under this proclamation, quality control, or other purposes regulated under this proclamation.

57/ "executive organ" means a body which is empowered to administer this proclamation at the federal government level.

58/ "executive body" means a governmental body which is empowered to administer this proclamation and other laws issued under this proclamation at the federal government level.

59/ "regional health regulator" means a regional government body which is empowered to administer this proclamation and other laws issued under this proclamation at the regional government level.

60/ "appropriate body" means, as applicable, the executive body or any other organs that have a legitimate interest in the course of implementation of powers granted under this proclamation.

61/ "Ministry" or "Minister" means the Ministry or Minister of Health, respectively.

62/ "person" means a natural and juridical person; and includes the feminine.

63/ any expression in the masculine gender includes the feminine.
3. **Scope**

This proclamation shall be applicable in respect of food, medicine, medical device, cosmetics, and tobacco product intended to be placed on the market or offered, in any other way, for use by the public, and other products and raw materials regulated under this proclamation.

**PART TWO**

**EXECUTIVE ORGANS**

4. **Power and duties of the executive organ**

The executive organ shall have the power and duties to:

1. initiate regulatory standards and implement standards issued regarding food safety; safety, efficacy, quality, and rational use of medicines; safety, quality, and effectiveness of medical devices; and other products regulated under this proclamation; adopt appropriate pharmacopeia from another country or manufacturer’s in house method;

2. issue, renew, suspend or revoke a certificate of competence or take another appropriate measure of an importer, exporter or quality control service provider, bioequivalence centers, and a manufacturer or wholesaler whose product is intended to be traded in more than one region;

3. evaluate and register medicine, medical device, food and other products that are required to be registered under this proclamation, or regulation or directive issued to implement this proclamation based on applicable requirements; issue, renew, suspend or revoke marketing authorization or take other appropriate legal measures;
1. prepare and issue necessary permit for regulated products, their raw materials and packaging materials.
2. issue import permits and, upon request, export certificates for regulated products.
3. prepare and issue necessary revised list of essential medicines, notify regulated food and their packaging materials.
4. prepare and issue necessary revised list of essential medicines, notify regulated foods and their packaging materials.
5. prepare and issue necessary revised list of essential medicines, notify regulated foods and their packaging materials.
6. identify ingredients that caused death, sickness, disability, disorder, or other health problems due to adulteration or other illegal activities on regulated products and take appropriate legal measures by conducting investigation of sample ingredients.
7. issue import permits and, upon request, export certificates for regulated products.
8. prepare and issue necessary revised list of essential medicines, notify regulated products and their raw materials and packaging materials.
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89. prepare and issue necessary revised list of essential medicines, notify regulated products and their raw materials and packaging materials.
90. issue import permits and, upon request, export certificates for regulated products.
9/ undertake or order post-marketing surveillance to ensure food safety; safety, efficacy and quality of medicines; safety, quality, and effectiveness of medical devices; and on other regulated products and take appropriate legal measures in accordance with the findings.

10/ ensure that evidence of existing and new adverse events and information about pharmacovigilance of globally monitored products are followed upon and, as appropriate take the necessary legal measure;

11/ authorize the conduct of clinical trial, monitor and inspect the process as to its conduct in accordance with good medical practice, evaluate the results and authorize the use of the result in such a way that benefit the public; order the clinical trial to be suspended or stopped;

12/ promote rational use of medicine and medical device;

13/ regulate the manufacture, import, export, distribution, prescribing, dispensing, use, recording and reporting of narcotic drug, psychotropic substance and precursor chemical, and prevent their abuse;

14/ regulate the cross regional advertisement of regulated products in cooperation with the appropriate government body;
15/ coordinate the implementation of the World Health Organization Framework Convention on Tobacco Control and its implementing guideline; establish national coordinating mechanism to follow-up effective implementation of tobacco control, and work in collaboration with appropriate bodies;

16/ regulate the content and product disclosure, manufacturing, packaging, labeling, design, import, storage, distribution, advertisement, promotion and sponsorship, and related aspects of tobacco products in line with the World Health Organization Framework Convention on Tobacco Control and its implementing guideline;

17/ ensure, in collaboration with appropriate bodies, proper disposal of expired and other non-complying product regulated under this proclamation;

18/ appoint inspectors, and, as appropriate, order the inspection of any premises in accordance with this Proclamation;

19/ collect service fee, and use the same in accordance with appropriate law for the purpose of health regulation.

PART THREE

FOOD SAFETY ADMINISTRATION

5. General

1/ Every food establishment who provides food for use by the public shall ensure its safety.
2/ The rigor of safety assessment of food shall be based on its type and potential risk to human health.

3/ Every food and packing material shall comply with Ethiopian standard adopted by the appropriate body.

4/ Notwithstanding sub-article (3) of this article, the executive organ may use acceptable Ethiopian standard adopted by international organizations to regulate the safety of food for which national standard is not issued.

5/ The executive organ or regional health regulator may request third party conformity assessment regarding the safety of food provided by food institution.

6/ Every food prepared for the purpose of exporting shall be safe and promote the country's sustainable trade interest.

7/ Every locally produced food for which mandatory standard is issued shall bear the applicable mark and shall possess a certificate issued for this purpose.

6. Registration of food and food trade establishment

1/ Every person shall be registered by the executive organ or regional health regulator before commencing a food trade activity.

2/ Unless authorized by the executive organ or regional health regulator, no food trade establishment may provide a pre-packed food for use by the public.
3/ Registration of food and food trade establishment shall be renewed within the time frame required by the executive organ or regional health regulator.

7. Food manufacturing, preparation, storage, transport or selling place

1/ Every food establishment shall have the responsibility to ensure that equipment or material used in food manufacturing, storage, or transport is clean and free from contaminants, and ensures that it complies with safety requirements issued by the executive organ.

2/ In addition to the responsibilities provided under sub-article (1) of this article, every food trade establishment shall have the responsibility to ensure that places for food manufacturing, preparation, storage, or sell are clean and far from contaminants.

3/ Every food establishment may use equipment or material with direct contact in the food only if it fulfills safety requirements and shall ensure that devices are periodically calibrated by an appropriate organ.

4/ It shall be the responsibility of every food establishment to ensure that food is stored, transported, or placed for sale in such a way that its safety is preserved and, if necessary, a proper cold chain is maintained.

5/ Any food product may not have chemical residue including pesticide, fertilizer, animal medicine, food additive chemical, cleaning chemical, a radioactive substance, and other contaminants above the maximum level issued or adopted by the appropriate organ.
6/ Every food establishment, depending on the nature of the food, has the obligation to give adequate information about handling and use of foods it offers to sell.

8. Personnel working in food establishments

1/ Every food establishment shall ensure that its employees who are engaged in the manufacturing, preparation, or service

a) who have a direct contact with the food to be free from food-borne illness and take appropriate measure to prevent food-borne illnesses; and

b) wore an appropriate safety clothing.

2/ Every person who participates in the manufacturing of food and has knowledge of or reason to believe that a significant risk to the public’s health exists shall immediately report, as appropriate, to the executive organ or regional health regulator.

9. Food manufacturing

1/ Every food establishment has obligation to install the required quality control system to ensure the safety of foods it produces.

2/ It shall be the responsibility of every food manufacturer, importer or preparer to ensure the safety of raw material used for food manufacturing.
3/ Every packaged food manufacturer shall report to the executive organ if it introduces change in the type, content, and manufacturing process of the food it produces.

10. Food import and export

1/ Food may be imported only when it complies with applicable safety standards and a permit is granted by the executive organ.

2/ Without prejudice to sub-article (1) of this article, if the executive organ has reason to suspect the safety of the food it may perform a laboratory test, or order a laboratory test to be performed by a third party and its cost covered by the importer.

3/ If any imported food has established safety problem, the executive organ may determine to evaluate good manufacturing practices of the manufacturer.

4/ Food found to be unsafe under this proclamation may be returned to its country of origin or be locally disposed at the expense of its importer.

5/ A food exporter, as necessary, may get health certificate of food it intends to export from the executive organ.

11. Food additive

1/ Use of maximum level of a food additive shall be in accordance with Ethiopian standard issued by the appropriate body.
2/ The executive organ shall determine the list of allowable food additives.

3/ The executive organ may, where appropriate, prohibit the use of food additives in a certain category of foods.

12. Infant formula and follow-up formula
Every infant formula and follow-up formula shall comply with applicable Ethiopian quality and safety standards; its component shall not be genetically modified and exposed to any radiation during manufacturing, and its packaging is made from a non-plastic material, and contains a label bearing the source of its protein.

13. Food supplement
1/ Food supplement may not be imported or placed on the market without registration.

2/ The rigor of safety assessment of food supplements shall be commensurate based on its type, potential risk to human health, and its health claim.

14. Food fortification
1/ Every food identified for fortification shall fulfill applicable Ethiopian standard adopted by the appropriate body.

2/ Vitamins, minerals, or other essential nutrients permitted for fortification purpose may only be used if it fulfills requirements set by the appropriate body.

3/ Every food manufacturer that fortifies food in accordance with sub-article (1) and (2) of this article shall accordingly label the food as fortified.
15. Food for irradiation

1/ Irradiation of food shall be carried out in such a way that it is designed to meet the requirement of food safety and using the appropriate type and limit of radiation.

2/ Regulation of irradiation requirement shall be implemented in cooperation with appropriate bodies.

16. Water safety

1/ Any pipe or bottled water or other potable water supplier or producer shall ensure compliance with the Ethiopian safety standard.

2/ The safety and effectiveness of every water treatment chemical or device shall be regulated by the executive organ.

17. Post-market safety monitoring

1/ Every food manufacturer or importer shall have a system to enable it to continuously monitor the safety of the food it produces or imported.

2/ If the public's health is in danger due to a confirmed safety problem relating to food manufacturing, storage, transport or handling, the executive organ or regional health regulator may notify the public through the appropriate massmedia not to use the food and order recall of the product.

3/ The executive organ shall periodically undertake safety monitoring of food products placed onto the market; and may order the cost be covered by its manufacturer or importer.
PART FOUR
MEDICINE, MEDICAL DEVICE AND COSMETIC'S ADMINISTRATION

Section One
Medicine and Medical Device Administration

19. General
1/ The rigor of regulatory assessment of medicine and medical device shall be commensurate with the product’s type, nature, and potential risk to human health.

2/ The executive organ may not limit the number of agents a manufacture may designate for the purpose of importing or distributing medicine or medical device.

18. Alcoholic drink Sale
1/ Every industrially prepared alcoholic drink shall comply with applicable Ethiopian or other international standard accepted by the country issued with regard to its content.

2/ It shall be illegal to sell any alcoholic drink to anyone under the age of 21.

3/ No person may sell alcoholic drink Health institutions, education facilities, kindergartens, universities and colleges, government institutions, places of worship, sporting places, cinema houses and other places determined by a regulation issued to implement this proclamation.

4/ Additional restrictions with regard to the time and manner of sale of alcoholic drink may be determined in accordance with a regulation issued to implement this proclamation.
The executive organ shall register any medicine or medical device imported for use by a particular patient as per prescription of an authorized medical professional.

Any medicine or medical device shall be registered if the manufacturer complies with good manufacturing practices, and as appropriate fulfill safety, quality, efficacy, and effectiveness, and as appropriate fulfill laboratory quality test requirements.

Any medicine or medical device shall not be registered if the manufacturer fails to comply with good manufacturing practices, and as appropriate fails to fulfill safety, quality, efficacy, and effectiveness, and as appropriate fails to fulfill laboratory quality test requirements.

The provisions of sub-article (1) of this article shall not apply in respect of the sale of any medicine compounded by a pharmacist for a particular patient in a quantity not greater than the quantity required for treatment as determined by an authorized medical professional, or any medicine or medical device imported for use by a particular patient as per prescription of an authorized medical professional.

Any other person without regulation by any other authority shall not be authorized to register any medicine or medical device.
5/ Notwithstanding to the provision of sub-article (1) of this article, the executive organ may, in compelling circumstances, grant a permit for the importation or use of unregistered medicine or medical device.

6/ Every medicine or medical device registered in accordance with this proclamation shall have its registration renewed every five years.

7/ Without prejudice to the provision of sub-article (6) of this article, any registered medicine or medical device shall pay annual retention fee as determined by a regulation.

21. Variation to a registered product

1/ If variation affecting registered medicine’s quality, safety or efficacy, or medical device’s safety, quality or effectiveness is introduced, the product may not be marketed unless the person who registers the product notifies such variation and gets approval from the executive organ.

2/ Without prejudice to the provision of sub-article (1) of this article, a medicine or medical device with variation having minimal potential on its performance may be marketed provided the manufacturer or the person who registers the product notifies the executive organ of such variation.

22. Quality standards and requirements

1/ Any medicine, its raw or packaging material shall meet quality, safety and efficacy requirements prescribed in a nationally accepted pharmacopeia.
2/ Any medical device shall meet quality, safety and effectiveness requirements issued or adopted by the appropriate organ.

3/ Notwithstanding to the provision of sub articles (1) and (2) of this article, where national standard is not issued or adopted, the executive organ may regulate medicine and medical device in accordance with requirements prescribed by international organizations, other countries, and requirements or guidelines issued by manufacturing companies acceptable to the executive organ.

23. Registration of medicine and medical device institution

1/ No medicine or medical device institution may engage in medicine or medical device trade unless it is registered and licensed, as appropriate, by the executive organ or regional health regulator.

2/ It shall be prohibited, in any manner, to transfer a medicine and medical device institution certificate of competence to a third party.

24. Personnel working in medicine and medical device institution

1/ Every medicine and medical device institution shall hire a health professional upon ensuring that the professional is duly registered and competent to perform the task.

2/ Every health professional working for a medicine or medical device institution shall have the duty to immediately report risks of public health significance related to the quality, safety and efficacy or
medicine or quality, safety and effectiveness of a medical device, as appropriate, to the executive organ or a regional health regulator.

25. Medicine and medical device manufacturing and importation

1/ The manufacturer of medicine or medical device shall have the duty to ensure the quality and safety of raw materials and the legality of its supplier.

2/ It shall be the duty of the manufacturer or importer, as appropriate, to ensure that every medicine or medical device is produced in accordance with the appropriate good manufacturing practice.

3/ No medicine or medical device may be imported through a port of entry unless authorization is granted by the executive organ.

4/ Every importer of a medicine or medical device shall be responsible for ensuring that its imported product is from a manufacturer recognized by the executive organ.

5/ If the quality, safety, and efficacy or effectiveness of a medicine or medical device are not in compliance with the law, the executive organ may order the manufacturer or importer, as appropriate, to properly dispose or return it to its country of origin.
26. Storage, transport, and sell of medicine and medical device

1/ The medicine or medical device institution or another appropriate person shall ensure that every product under its possession is stored, transported, and sold in accordance with good storage and distribution practices and in such a way that its quality, safety, and efficacy or effectiveness is maintained.

2/ Every manufacturer, importer, wholesaler and retailer of a medicine or medical device shall install a quality control system that ensures the safety and quality of the product.

3/ Every part of a transportation equipment having direct contact with the medicine or medical device shall be clean and shall not render the product to cause any chemical, physical, or microbiological contamination.

4/ No medicine or medical device institution may transfer any medicine or medical device under its possession outside of the recognized trade chain without having a legitimate ground and, as appropriate, notifying the executive organ or regional health regulator.

5/ A retailer of medicine or medical device shall not engage in the wholesale trade of any medicine or medical device.

6/ No medicine wholesale or retail institution may sell a medicine unless its label contains the retail price of the product affixed by the manufacturer or importer in
It shall be the responsibility of the health institution to ensure that the type of medicine it possesses are in accordance with its level, and the health professional who has access to the medicine has appropriate authorization.

27. **Clinical trial**

1/ A clinical trial shall be conducted on human beings only in accordance with this proclamation and directive issued to implement this proclamation.

2/ The executive organ shall authorize clinical trial on human subjects only after the clinical trial protocol is evaluated and accepted from scientific, legal and ethical perspective.

3/ It shall be prohibited to introduce any change to the terms and conditions of an approved clinical trial protocol unless the executive organ is duly notified.

4/ The executive organ may require review and monitoring of the approved clinical trial study by an appropriate national, regional or institutional review organ.

5/ Clinical trial on human beings shall be conducted if the person is over 18 years, has capacity under the Ethiopian Civil Code, and agree in writing to the clinical trial.

6/ Clinical trial on nursing and pregnant women, prisoner, person under the age of 18, mentally ill person, other judicially incapable person, or person dependent on the professional or the institution
conducting the clinical trial shall be prohibited unless there is a necessary ground and a special permission granted by the executive organ in accordance with applicable regulation.

7/ It shall be the responsibility of the primary investigator and sponsor of the clinical trial to ensure the safety of the participant, provide adequate information to prospective participants about the risks, medical benefits, and treatment alternatives available to the participant.

8/ It shall be the responsibility of the primary investigator and sponsor of the clinical trial to ensure appropriate scientific conduct, making required reports to the executive organ, record keeping, reporting any adverse event, and adhering to applicable protocol, practices, and laws.

9/ In approving investigational medicine or medical device, the executive organ may require submission of laboratory experiment and animal testing data in order to determine its safety.

10/ The use of investigational medicine or medical device beside clinical trial shall have prior approval from the executive organ.

11/ A Clinical Trial Ethics Committees Supervisory Body directed by a higher official of the executive organ shall be established.
28. Antiseptics and disinfectants

1. Every regulated person shall comply with applicable requirements issued about antiseptics and disinfectants.

2. The registration and related regulatory assessment of antiseptics and disinfectants shall be commensurate with the product’s potential risk to human health.

29. Radio-pharmaceutical and radiation emitting medical device

1. No one may manufacture, import, export, wholesale or store any radiopharmaceutical or radiation emitting medical device unless he gets a certificate of competence from the executive organ and appropriate body.

2. Extemporaneous preparation of a radiopharmaceutical product may only be carried out in a health facility having a certificate of competence to perform this activity.

3. In effectively regulating radiopharmaceuticals or radiation emitting medical device, the executive organ shall work together with the appropriate body.

30. Blood and blood components

1. Any person who engages in the collection and distribution of blood and blood products shall get a certificate of competence from the executive organ.

2. Blood and blood products donation, collection, and distribution shall be performed in accordance with principles of
humanity, and such products used for the purpose of saving life or scientific research may not financially benefit both the donor and recipient.

3/ Blood and blood components for transfusion or further manufacturing or processing may not be put into use unless its safety and quality are in compliance with applicable regulatory requirements.

4/ Blood activities shall be classified and regulated based on its potential risk to the safety of whole blood and blood components, the donor, and the recipient.

5/ Every potential risk associated with blood donation shall be communicated to the donor and the recipient of transfusion.

6/ Health facilities, laboratories, blood banks and other establishment engaged in blood and blood component activities shall make sure it is collected, tested, processed, screened, pooled, irradiated, washed, stored, labeled and distributed in accordance with applicable regulatory requirements.

31. Narcotic and psychotropic medicines, and precursor chemicals

1/ A special permit from the executive organ shall be a prerequisite to manufacture, import or export any narcotic and psychotropic medicines, or precursor chemical.

2/ Anyone who engages in manufacturing, import, export, wholesale, store, transport, hold or sell any narcotic and psychotropic medicine, or precursor chemical shall comply with this proclamation, and regulation and directive issued to implement this proclamation.
3/ A special permit for the import or export of narcotic and psychotropic medicines, or precursor chemical 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 and psychotropic medicines, or precursor chemical through the post office or by ship; or packed together with other medicines or goods.

5/ Narcotic and psychotropic medicines 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 pharmacy professional.

6/ Every manufacturer, importer, wholesaler, retailer, or health institution involved in narcotic and psychotropic medicines, or precursor chemical activities shall keep relevant records, perform demand projections, and submit reports in accordance with directive issued by the executive organ.

7/ Any person who gets narcotic and psychotropic medicines, or precursor chemical purchase order from the executive organ shall report when the product is imported, or if it is not imported for whatever reason it shall be reported within ten days from the expiration of the purchase order.
32. Prescription of narcotic and psychotropic medicines

1/ Any licensed medical professional may only issue narcotic and psychotropic medicines prescription in the health institution where he is authorized to work.

2/ No medical professional may prescribe narcotic and psychotropic medicine for himself.

3/ The prescription of a narcotic or psychotropic medicine shall be made on a special narcotic or psychotropic prescription paper respectively.

4/ If any medical professional made a mistake on the narcotic or psychotropic prescription paper, he shall fold away and leave the leaf paper containing the error intact within the prescription folder.

5/ After issuance of the original of any narcotic and psychotropic prescription to the patient, its copy shall remain in the prescription folder.

6/ Every folder containing a copy of prescribed narcotic and psychotropic medicines shall be returned, as appropriate, to the executive organ or regional health regulator.

7/ Provisions of this proclamation provided in respect of dispensation of prescription medicines shall be applicable to narcotic and psychotropic medicines, as appropriate.

8/ It is prohibited to prescribe more than one narcotic and psychotropic medicine on one prescription paper, prescription paper shall have no effect after fifteen days from the day it is prescribed.
33. Dispensing narcotic or psychotropic medicine

Every authorized health institution and medicine retailer may only dispense a narcotic and psychotropic medicines upon confirmation that:

1/ the prescription paper contains the name of the prescriber and the institution’s stamp;
2/ the prescription is original, and the writing or print on the paper does not contain an error;
3/ narcotic and psychotropic medicine is prescribed using narcotic and psychotropic medicine prescription paper respectively;
4/ no more than one type of narcotic and psychotropic medicine is not prescribed using one prescription paper;
5/ the prescription paper contains readable series number; and
6/ the issue date is within the past fifteen days.

34. Medicine compounding

1/ Medicine compounding shall only be performed by an authorized pharmacy professional and within an authorized institution.
2/ It shall be the responsibility of the pharmacy professional to ensure that any compounded medicine prepared for a patient in accordance with a prescription issued by a medical professional does not contain an unapproved ingredient in accordance with applicable law or standard and is not unusually harmful to the user.
3/ Every pharmacy professional who is authorized to perform medicine compounding shall ensure that any active pharmaceutical ingredients used to compound a medicine are an authorized component in other medicine registered by the executive organ.

4/ The pharmacy professional, health institution, or medicine trade institution shall be jointly and severally responsible for any health or bodily harm caused as a result of using the unapproved active pharmaceutical ingredient.

35. Medicine prescribing and prescription paper

1/ Medicine may only be prescribed by an authorized medical professional.

2/ Every medical professional shall prescribe a medicine in accordance with the appropriate prescription paper and uniform medical service and prescription procedure.

3/ Every medical professional shall prescribe a medicine by using its generic name; Exceptions shall be provided by regulation or directive issued to implement this proclamation.

4/ Every medical professional authorized to prescribe a medicine shall ensure that all required information in the prescription paper is filled out.

5/ The amount and manner of anti-microbial medicine prescription shall comply with the uniform medical service delivery requirements.
6/ Unless for emergency situations a prescription shall be given only after the patient has got a medical record and the prescription information is sufficiently provided in the record.

36. Medicine dispensing, and over the counter medicines

1/ Medicine shall only be dispensed by a pharmacy professional acting within his scope of practice.

2/ Notwithstanding to the provision of sub-article (1) of this article, the executive organ, by a directive, shall determine compelling circumstances when dispensing by other health professional categories may be appropriate.

3/ Every medicine dispensing shall be made as per the paper or electronic prescription.

4/ Notwithstanding to the provision of sub-article (3) of this article, the executive organ shall determine a list of over the counter medicines to be sold in medicine retail shops.

5/ Every pharmacy professional may dispense a generic medicine prescribed using its brand name. Special circumstances may be determined as per a regulation or directive issued to implement this proclamation.

6/ While dispensing a medicine, every pharmacy professional shall ensure that the patient is informed about the identity, use, instruction for use, precautions, side effects, and other relevant information about the dispensed medicine.
7/ It shall be prohibited to dispense or sell, in any way, expired, damaged, substandard, diverted or illegal medicine.

8/ The pharmacy professional shall ensure the legality and completeness of a paper or electronic prescription before any dispensation.

9/ After dispensation of medicine in accordance with this article, the information provided under the prescription shall be logged into a paper or electronic logbook prepared for this purpose, and the prescription shall be filed after being stamped, named, signed and dated by the prescriber.

10/ Every professional shall notify the regional health regulator or executive organ or health regulators at different level when he knows of defects associated with the quality, safety, and efficacy of medicine.

37. Classification of medicine and medical device

1/ The classification of any medicine and medical device shall be determined by the executive organ based on the nature of the product and standard of the health institution.

2/ The classification of medicine issued in accordance with sub-article (1) of this article shall be as follows:

a) medicine that will be available on the advice of a pharmacy professional, without a prescription from an authorized prescriber, and available only in authorized medicine retail institution:
b) medicine that will be available only on the prescription of an authorized medical professional, and dispensed by a pharmacy professional;

c) medicine that will be available only on the prescription of an authorized medical professional and dispensed by a pharmacist professional, and subject to the control measures prescribed in accordance with the United Nations Conventions on narcotic drugs, psychotropic substances, and illicit traffic in narcotic drug or psychotropic substances;

d) medicine classified in accordance with the standard of health institutions, and

e) medicines that will be used for rare diseases or conditions.

38. Post marketing surveillance

1/ Every manufacturer and importer, as appropriate, shall perform periodic monitoring of the quality, safety, and efficacy or effectiveness of its manufactured or imported medicine and medical device.

2/Every manufacturer, importer, or wholesaler of a medicine or medical device shall, when required by the executive organ or on its own will, perform a postmarketing surveillance that would enable it to continuously monitor its medicine or medical device; establish a vigilance system, and furnish adverse event information and other required information.
3/ The executive organ may periodically undertake post-market surveillance of medicine and medical devices and may require its manufacturer or importer, as appropriate, to cover the associated cost. Implementation details shall be determined by regulation.

4/ The manufacturer or importer of any medicine or medical device shall be responsible for damages caused as a result of quality and safety problems associated with the product. Implementation details shall be determined by regulation.

39. Prevention of Illegal medicine and medical device circulation

1/ Any person involved in the business of medicine and medical device trade shall take every precaution to ensure the legality of its suppliers, use legal receipt, and make an immediate report to the executive organ and other appropriate law enforcement organ when the illegality of the medicine and medical device is known to him.

2/ Every medicine and medical device found to be illegal shall be confiscated by, as appropriate, the executive organ or regional health regulator.

3/ Without prejudice to the provision of sub-article (2) of this article, the executive organ or regional health regulator together with the appropriate body shall ensure the appropriate disposal of confiscated medicine and medical devices.
4/ The executive organ or regional health regulator shall pay a cash reward to any person who gives information leading directly to the apprehension of an illegal medicine or medical device.

40. Refurbished and remanufactured medical device

Every refurbished and remanufactured medical device shall:

a) have a permit from the executive organ;

b) contain, on its labeling, the word "refurbished or remanufactured" as appropriate, and a user manual; and

c) mention the length of its prior use or date when it is refurbished or remanufactured.

41. Public health pesticides

1/ No person may manufacture, import, export, wholesale, or sell public health pesticide unless the executive organ or a regional health regulator grants certificate of competence.

2/ Any person who has a certificate of competence in accordance with the provision of sub-article (1) of this article shall keep and transmit relevant record with regard to the public health pesticide it manufactures, imports, distributes, or sales to the executive organ or regional health regulator.

3/ Any person who gets a certificate of competence in accordance with this provision shall be responsible for monitoring and ensure every public health pesticide is packaged, transported, stored, or distributed with the least possible risk to human, animal, and the environment.
The labeling of every public health pesticide shall at least be in Amharic language.

The executive organ shall work with other appropriate bodies to ensure the manufacture, transport, storage, use, and disposal of public health pesticide does not pose a threat to public health.

Section Two

Cosmetics

42. General

Every cosmetic product placed on the market shall not harm human health when used ordinarily or as intended.

43. Registration of trade institution

Every manufacturer, importer, and distributor of cosmetic shall be registered by the executive organ.

44. Cosmetic Notification and ingredients

1/ No one may manufacture or import to trade a cosmetic product unless a list of the cosmetic and related information is submitted in accordance with the operational procedure of the executive organ.

2/ A cosmetic may not contain any prohibited ingredients or any ingredient above the maximum level established by an applicable regulatory requirement.
Whenever it is necessary to protect public health, the executive organ may ban a cosmetic product or its ingredient.

Every manufacturer or importer shall be responsible for any damage caused as a result of the cosmetic it manufactured or imported.

Manufacturing, storage, transport, and sale of cosmetic

1. Every manufacturer of a cosmetic product shall make sure that its product is produced in accordance with applicable good manufacturing practices.

2. The manufacturer, importer, distributor, or retailer of every cosmetic shall ensure the safety of the product during storage, transport, and sale.

3. It shall be prohibited to manufacture, import, store, distribute, transport or sell any cosmetic or cosmetic raw material that is not in compliance with this proclamation or other applicable regulatory requirements.

4. Every storage and transport equipment, having direct contact with the cosmetic product, shall not cause chemical, physical, and microbiological contamination.

PART FIVE
TOBACCO AND RELATED PRODUCTS ADMINISTRATION

46. Tobacco product special license and related products

1. No person may manufacture, import, wholesale, or distribute any tobacco products without having a special license from the executive organ.
2. Tobacco products content and disclosure

Every tobacco grower and manufacturer shall have the obligation to prevent and control potential harms caused on the health of employees or the environment as a result of tobacco growing or manufacturing.

3. Tobacco products content and disclosure

No one may manufacture, import, wholesale, distribute, sell, or offer to sell any tobacco product that:

a) has a characterizing flavor, whether or not the product packaging indicates that the product has a characterizing flavor;

b) contains a flavoring in any of its components or the packaging, wrapping or any technical feature of the product allowing modification of the smell or taste of the product;
c) contains one or more additives with properties associated or likely to be associated with energy or vitality, a health benefit, or reduced health risk, such as but not limited to, amino acids, caffeine, taurine or other stimulants, vitamins, and minerals, or is represented or suggested as containing any such additives or as having such properties;

d) contains a colorant to change the color of tobacco smoke; or
e) does not conform to other tobacco product requirements adopted by the executive organ.

48. Prohibition of smoking and tobacco use in public places

1/ No person may smoke or use tobacco products in any part of all indoor workplaces, all indoor public places, on all means of public transport, and in all common areas within condominium housings.

2/ No person may smoke or use tobacco in any outdoor space that is within ten meters of any doorway, operable window, or air intake mechanism of any public place or workplace provided under sub-article (1) of this article.

3/ Notwithstanding to sub-article (2) of this article, smoking in any outdoor part of healthcare facilities, government institutions, facilities including schools...
intended mainly for children or youth under the age of 21, higher education institutions, youth centers, amusement parks, and any other places as determined by the executive organ or regional health regulators shall be prohibited.

49. Tobacco products sale

1/ The sell of tobacco products by and to any person under the age of 21 shall be prohibited.

2/ It shall be prohibited to sell tobacco products within hundred meters of the premise of health institutions, schools, and youth centers, where smoking and tobacco use is prohibited under this proclamation.

3/ No person shall sell or arrange for tobacco products to be sold or enable or facilitate such sale, by any other means, including via the internet, mail or telecommunication or through any means by which the purchaser and seller are not in the same physical location.

4/ Tobacco products may only be sold in intact packages containing 20 sticks or consisting of the specified weight as prescribed by the executive organ.

5/ It shall be prohibited to manufacture, import, store, wholesale, distribute, sell, or offer to sell any shisha product. A trade activity that is intended to provide a place for smoking of shisha or other tobacco products shall be prohibited.
50. Duty to enforce tobacco-free provisions

1/ It shall be the duty of the owner or another appropriate person in charge of the management of the public place or public conveyance for which tobacco smoking, use or sale is prohibited to ensure that no one smoke, use, or sale any tobacco product, and to ban the placement of an ashtray or other comparable devices intended for tobacco use in such places.

2/ The owner or another responsible person of the public place or conveyance, or, in the case of a workplace, the employer or another appropriate person, shall post clear and prominent notices regarding the prohibition of tobacco smoking and use along with its corresponding "no-smoking" sign.

51. Protection against tobacco industry interference

1/ Interactions between any government organ responsible for the adoption of public health policy and the tobacco industry shall be limited to only those strictly necessary for effective regulation of the tobacco industry or tobacco products.

2/ Any interaction made in accordance with sub-article (1) of this article, and whenever the tobacco industry contacts the government to initiate an interaction of any kind, the appropriate government official shall ensure full transparency of the interaction and of the contact, and it shall be appropriately documented.

3/ No person having financial or other interest in the tobacco industry may participate in tobacco control training, workshop, or related events unless in accordance with an invitation by the relevant health regulator.
4/ No government organ or an official working in the area of health policy should receive any financial or in-kind contribution from the tobacco industry. A government organ may receive contribution from the tobacco industry in accordance with sub-article (5) of this article.

5/ Any financial or in-kind charitable or any other related contribution by a tobacco industry shall be prohibited.

52. Tobacco taxation, and prevention and control of illicit trade in tobacco products

1/ The federal government organ responsible for initiating the country’s tax policy shall levy a tax on tobacco products consistent with the World Health Organization Framework Convention on Tobacco Control which Ethiopia has ratified.

2/ The responsible government shall control illicit trade in tobacco products in accordance with the World Health Organization Framework Convention on Tobacco Control which Ethiopia has ratified.

PART SIX
LABELING, PACKAGING, ADVERTISEMENT, PROMOTION, AND PROHIBITIONS

53. General

1/ Any product regulated under this proclamation:

a) shall be appropriately packed and contain labeling on its primary packaging;

b) its packaging material shall not contaminate the product and comply with standard issued by the appropriate body; and
(c) its labeling shall not be misleading and contain information that is inaccurate.

2/ The primary packaging of a packed food and cosmetic shall have a label in Amharic or English language. The executive organ may by a directive determine labeling requirement different from Amharic or English language, or the primary packaging.

3/ The insert labeling of medicine that is included in the national essential medicine list or widely circulated in the market shall be in Amharic and in English. If the intended distribution of the medicine is limited to one region, its insert labeling shall be, at least, in English and the region’s working language.

4/ Notwithstanding to sub-article (3) of this article, the executive organ by a directive shall determine different labeling requirement other medicine and medical devices.

5/ No person may import or place into use of any medicine or medical device unless its labelling contains a barcode.

6/ Every manufacturer or importer shall provide the labeling of its cosmetic when making notification to the executive organ.

7/ The manufacturer or importer of a medicine shall, affix the medicine retail price, in Ethiopian currency, on its labelling before placing the product on the market.
54. Food packaging and labelling

Without prejudice to general labeling provisions provided under this part:

a) Fortified food labeling shall contain description about the type of micronutrient used to enrich the food;

b) Labeling, description, or advertisement of any food supplement shall not represent to be used in disease prevention, treatment, or cure, or in any way characterize as a medicine;

c) A food containing genetically modified element may only be placed on the market if it is packaged and its label contains the phrase "genetically modified" or other comparable description.

d) Labeling of irradiated food shall contain the phrase "irradiated" or the internationally accepted radura symbol indicating a food product has been irradiated with ionizing radiation may be placed besides the labeling.

e) If the food product contains milk and milk products, fish and shellfish, wheat, barley, peanuts, soybeans, and other food allergenic its labeling shall clearly describe its content.
The label of every alcoholic drink prepared at a factory level and provided for public use shall contain its alcoholic volume and a warning that alcohol consumption may cause health problems and women should not drink alcoholic drinks during pregnancy because of the risk of birth defects. Where the alcohol content of the drink is equal to or less than 10%, the expiry date of the product shall be provided under the product label. The label of every in-vitro medical device shall contain the phrase "for medical use".

The labeling of radiopharmaceuticals and radiation emitting medical devices shall contain information sufficient for the patient and users to identify radiation protection methods, inappropriate use, and possible risks associated with the installation of the product, as appropriate.

The labeling of medical devices is intended for research, education, clinical trial, or any other comparable non-medical use. Its labeling shall contain the purpose for which it is intended to be used.

Where the medicine or medical device is intended for research, education, clinical trial, or any other comparable non-medical use, its labeling shall contain the purpose for which it is intended to be used.

The label of every alcoholic drink prepared at a factory level and provided for public use shall contain its alcoholic volume and a warning that alcohol consumption may cause health problems and women should not drink alcoholic drinks during pregnancy because of the risk of birth defects.

The label of every alcoholic drink prepared at a factory level and provided for public use shall contain the product's expiration date.
57. Tobacco products health warnings, packaging, and labeling

1/ The packaging of any tobacco product shall contain rotating health warnings and messages that are comprised of combined images and full-color pictures in accordance with requirements set by the executive organ.

2/ The health warnings and messages required in accordance with sub-article (1) of this article shall be displayed on no less than 70% of the front and back side of each principal display area of its packaging and labeling, not counting the space taken up by any border surrounding the health warning.

3/ Any misleading statement or presentation on the outside packaging and labeling of tobacco products with the likely effect to create an erroneous impression about the product’s characteristics, health effects, hazards or emissions, or any expression or presentation purporting to signify one tobacco product has lesser harm compared to other tobacco product shall be prohibited.

4/ Any term, descriptor, trademark, figurative, color, or other sign of any kind that directly or indirectly creates or is likely to create the false impression that a particular tobacco product is less harmful than others, including the terms “low tar”, “light”, “ultra light”, or “mild”, “extra”, and “ultra” and similar terms or expressions shall be prohibited.

58. Advertising and promotion

1/ The content of every advertisement and promotion of a regulated product shall not be false and misleading, be appropriate and ethical, and comply with requirements of this proclamation and other applicable laws.
2/ Every mass media and advertisement disseminator shall have the duty to comply with a directive issued in accordance with this proclamation.

3/ The advertiser and advertisement disseminator of any regulated product, and if the subject is promotion, the distributor or another person who caused the distribution of any promotional materials which includes medicine and medical device promotion agent, shall have joint and several responsibilities with regard to compliance with this proclamation and other applicable laws.

4/ Infant formula may not be advertised through any advertisement dissemination means except for the labeling on the product.

59. Medicine and medical device advertising and promotion

1/ Unless subject to exceptions defined under a directive issued by the executive organ, it shall be illegal to advertise any medicine through a means of advertisement dissemination.

2/ Any direct advertisement or promotion made in-person to a health professional shall be through a medicine or medical device promoter who is duly authorized by the executive organ.

3/ Unless it falls under the maximum allowable gift or giving as defined by a directive issued to implement this proclamation, it shall be prohibited to offer or give, directly or indirectly, any financial, in-kind or comparable benefit to a health professional in relation to promotion to health professionals.
4/ It shall be illegal to advertise medicine and medical devices or promote within health institution unless the appropriate executive organ grants permission to the advertisement.

60. Alcoholic drink advertising and promotion

1/ Any advertisement of an alcoholic product shall contain a warning, as appropriate in writing or sound, that it is illegal to sell it to a person under the age of 18.

2/ It shall be prohibited to directly or indirectly advertise alcoholic drinks in places of public gathering and sporting: street, condominium and other places by unreasonably decreasing the size of the warning.

3/ Any manufacturer, importer or distributor of alcoholic drinks whose volume is more than 10% shall not directly or indirectly sponsor public and government holiday, exhibition, sports event, school event and other related youth-centered events.

4/ Advertising any alcoholic drink through board is prohibited. This restriction shall be applicable on any direct or indirect advertisement that connects a brand name, emblem, trademark, logo, organizational embalm, or any other distinctive feature of alcohol product with non-alcoholic products, services, or matters.
5/ It shall be prohibited to advertise alcoholic drink by associating it with any lottery system or through billboard. Details shall be determined by regulation or directive issued to implement this proclamation.

6/ Additional restriction regarding the time, place, and manner of alcohol advertisement and promotion may be determined by a regulation issued to implement this proclamation.

61. Tobacco products advertising, promotion, and sponsorship

1/ Unless it is legitimate expression as defined by a directive issued to implement this proclamation, all direct or indirect tobacco products advertising, promotion or sponsorship shall be prohibited.

2/ Without prejudice to sub-article (1) of this article, no person may

a) initiate any tobacco products advertising, promotion, or sponsorship;

b) produce, publish, distribute, or make accessible any tobacco products advertising, promotion, or sponsorship content; or

c) engage or participate in any tobacco products advertising, promotion, or sponsorship as media or event organizer, celebrity or other participant, as a recipient of any sponsorship contribution, or as an intermediary that facilitates any such contribution.
3. Tobacco products in retail shops shall be placed behind or under the counter so that any customer may not directly grasp or see the product.

62. Prohibitions

Without prejudice to other prohibitions defined under this proclamation and other appropriate laws, the following acts are prohibited:

1. The doing of any act which causes a regulated product to be adulterated, misbranded, counterfeited, and substandard;

2. Poisoning a food by mixing any substance that is deleterious to human health;

3. The trading of or provision to the public of any adulterated, sub-standard, misbranded, and counterfeit product;

4. The receipt to trade a regulated product that is adulterated, sub-standard, misbranded, counterfeit, and the delivery or proffered delivery thereof for pay or otherwise;

5. The refusal or obstruction of inspection and related activities as authorized under this proclamation;

6. Mobile sale of medicines and medical devices; and

7. Conducting trade in regulated products in contravention to regulations, directives or other laws issued to implement this proclamation.
PART SEVEN

POWER, FUNCTION, AND RESPONSIBILITY OF INSPECTORS

63. Power and responsibilities

An inspector of the executive organ or regional health regulator, subject to the power and responsibilities of the agency where he works, shall have the power and duties to:

1/ enter, during working hours, in any licensed institution which holds any regulated product and conduct investigation and order its temporary closure; order a regulated product to be kept separately until laboratory result is known; to detain and seize, or order the storage without removal or alteration of, any product or another thing related to the product;

2/ If the institution or place where the regulated product is held is not registered by the executive organ or regional health regulator, enter with a court order and take legal measures;

3/ to stop any vehicle or other means of transport in which the inspector knows it carries non-complying regulated products, and open, search, take sample of the product, and detain or seize the product;

4/ inspect regulated products and raw materials at ports of entry and exist;

5/ enter, inspect and take legal measures, without court order, into a licensed institution during its off work hours and any other place if it held a regulated product which the inspector has sufficient reason to believe that it endangers public health and the product or other evidence is likely to disappear, be altered, or concealed, and notify such action to a nearby court of law;
6/ to examine, open, or test a product, equipment, tools, materials, or anything the inspector reasonably believes is used or capable of being used for illicit trade in the regulated product;

7/ to examine and make copies of or from any documents, notes, files, including electronic files, or other records the inspector reasonably believes might contain information relevant to determining compliance with the law; take samples or component of a product, measurements, photographs, and video of a regulated product;

8/ to order laboratory examination through the executive organ or regional health regulator of any product the inspector reasonably believes might be adulterated, counterfeit, noncompliant or otherwise dangerous to public health and, until the laboratory result is known, quarantine such items for a period of time as defined by regulation issued to implement this proclamation;

9/ inspect the proper disposal of regulated products when they expire or when they are confirmed to be unfit for use in accordance with this proclamation; and

10/ to enter any time in any public place where tobacco smoking or use is prohibited, and during working hour in any workplace, public conveyance and other places where tobacco smoking and use is prohibited conduct inspections and take legal measure.
Every inspector:

1/ before conducting any inspection activity, shall present his identification card or credential, and introduce his identity and organization, the reason for the visit and legal power to enter and inspect regulated products and institutions.

2/ shall recognize, collect and present admissible evidence including sample, measurement, a copy of a document, photograph, video recording and a copy of records to support an appropriate legal measure on the institution.

3/ shall, while exercising his powers and responsibilities, take due care to act within the legal limit, in accordance with applicable laws and codes of ethics, and in a reasonable manner to achieve the purpose of this proclamation.

4/ shall report to the executive organ or regional health regulator any non-compliance known to him with this proclamation and other laws issued to implement the proclamation.

5/ shall respect orders from higher official and discharge responsibilities with the necessary care, diligence, honesty, and timeliness.

6/ shall maintain the confidentiality of every information and document he gets due to his responsibility.

7/ shall observe new work procedure that is adopted by the executive organ or regional health regulator and intended to implement its power and responsibilities efficiently.
PART EIGHT
ADMINISTRATIVE MEASURE AND PENALTY

65. Administrative measures

1/ Where a regulated product or a holder of a certificate of registration, certificate of competence or other license is found in any way to be in violation of this proclamation or other applicable laws, the executive organ or regional health regulator shall take, depending on the severity of the non-compliance, one or more of the administrative measures defined under this article.

2/ A warning letter may be issued to any person who unintentionally violates the provision of this proclamation or other law issued to implement this proclamation for the first time, and the non-compliance does not cause any harm to human health, body, or life.

3/ If the non-compliance committed by any regulated person would cause minor harm, as defined by a directive to implement this proclamation, its registration certificate, certificate of competence, or other license may be suspended, and it may be revoked if the violation would cause major harm to human health, body, or life.

4/ Where any regulated product is suspected to violate applicable requirements and there exist a reasonable ground to doubt the non-compliance, it may be detained until laboratory or other examination is performed on the sample.
5/ Where any regulated product is confirmed to violate applicable regulatory requirements it may be, as appropriate, seized, confiscated, or disposed or returned to its country of origin at the owner's cost.

6/ Notwithstanding to sub-article (5) of this article, the product in appropriate circumstances, may be detained at owner's expense until such time if relabeling, repackaging, or similar other corrective measures would place the product in compliance with this proclamation.

7/ Where a regulated product is in contravention of applicable laws and, the use or exposure to this product will have adverse health consequences or would result in death the responsible person shall be ordered to recall their marketed products and to immediately cease distribution.

8/ The import of a regulated product that is found to be frequently non-complying with this proclamation or other applicable laws may be temporarily or permanently barred.

9/ When a person is criminally convicted due to act that is directly related to works in regulated products or services under this proclamation, the executive organ or regional health regulator may debar such person from engaging in such works.

10/ The executive organ and regional health regulator, in accordance with a regulation issued to implement this proclamation or other appropriate law, may take a civil penalty independently or together with another administrative measure.
66. Complaint on administrative measure

1/ A complaint-handling organ shall be established by the executive organ or regional health regulator to handle complaints when a regulated person who believes that any administrative measure that was taken on its product, institution or itself, or the denial of a legitimate service under this proclamation inappropriate, not proportional or illegal.

2/ The complainant shall have the right to be heard by the complaint handling organ established in accordance with this article, and may lodge a written complaint, proffer evidence, respond to answer, and request copy of decision.

3/ Any complaint to be made in accordance with this article shall be lodged within 30 working days from the date of final decision by the process owner of the executive organ or regional health regulator or from the date of confirmation of the decision by the higher official of the executive organ or regional health regulator. The complaint, however, may be directly brought before the complaint handling organ, if the higher official of the executive organ or regional health regulator doesn’t decide it within 5 working days.

4/ The complaint handling organ that received a complaint in accordance with subarticle (1) of this article shall render its decision within 60 working days from the date it receives a complete complaint.

5/ A final decision rendered by the complaint handling organ in accordance with this article may be appealed to the appropriate court of law.
67. Penalty

1/ Any person who, by sub-standardizing, misbranding, or counterfeiting a regulated product, manufactures, import, store, wholesale or sell it in retail; or provide or distribute for use by the public shall be punishable by simple imprisonment for not exceeding three years and a fine not exceeding Birr two hundred thousand. If the product’s defect would cause grave harm to human health or life, he shall be punishable by imprisonment not exceeding seven years and a fine not exceeding Birr five hundred thousand.

2/ If, due to the action described under sub-article (1) of this article,

a) harm is caused on the body or health of any person, he shall be punishable by imprisonment from seven years to fifteen years, and a fine from Birr twenty thousand to Birr three hundred thousand.

b) any person died, he shall be punishable by imprisonment from ten years to twenty years, and a fine from Birr thirty thousand to Birr four hundred thousand.

3/ If the person commits the crime described under sub-article (1) and (2) of this article negligently, he shall be punished by imprisonment for not exceeding three years and with fine not exceeding Birr fifty thousand.

4/ Any person who, without a registration, marketing authorization, certificate of competence or other authorization as required under this proclamation and other
law issued to implement this proclamation, or using a falsified document, manufactures, import, store, wholesale or sale it in retail; or provide or distribute for use by the public. shall have its product confiscated and be punishable by imprisonment from three years to five years and with a fine from Birr five thousand to Birr one hundred thousand. If the crime provided under sub-article (1) and (2) of this article is committed without a certificate of competence or using a falsified document the penalty of this article shall be additionally applicable.

5/ Any person who has a registration certificate, marketing authorization, certificate of competence or other license under this proclamation and other law issued to implement this proclamation and transfers the same to a third person, or anyone who received such document illegitimately shall be punishable by imprisonment from one year to five years and with a fine from Birr ten thousand to Birr one hundred thousand.

6/ Any person who, in any way, prevents or impedes the work of inspector as assigned under this proclamation, or in any way obstruct inspectors from getting evidence or hide or conceal such evidence from inspectors, give false statement or documents during their work, or attempts to do the preceding acts shall be punishable with imprisonment from one year to five years. If it causes harm to the person, body.
or possession of an inspector assigned under this proclamation and who is on duty shall be punishable by imprisonment from three years to fifteen years.

7/ Any person who sales medicine, medical device or related products without having the necessary qualification, or causes the sale or offer for sale of such product by unqualified person shall be punishable from three years to seven years and a fine from Birr ten thousand to Birr one hundred thousand.

8/ Any person who prescribes, sales, dispenses, or gives medicine without prescription or with unauthorized prescription in contravention to this proclamation and other laws issued to implement this proclamation shall be punishable by imprisonment from one year to five years, and with fine from Birr five thousand to Birr fifty thousand.

9/ Any inspector who, in relation to his authority under this proclamation,
   a) intentionally fails to report substantive facts, evidence, or inspection findings to the executive organ or regional health regulator, and as a result, a person’s health or body is harmed, shall be punishable with imprisonment from one year to three years and with a fine.
   b) made false report inspection findings to the executive organ or regional health regulator, or did not take the appropriate measure in a circumstance that guarantees administrative measure, or unjustifiably took a minor measure that is not proportional to the magnitude of the noncompliance shall be punishable with imprisonment from one year to three year
Where the crime defined under this sub-article (a) and (b) is committed negligently, it shall be punishable by imprisonment from six months to one year.

d) where the inspector under (a) and (b) of this sub-article commits the crime, the appropriate anti-corruption provision shall be applicable.

e) any person who contravenes the provision that requires health examination and health certificate for employees having direct contact with food preparation shall be punishable by imprisonment not less than three months and a fine from Birr twenty thousand to Birr fifty thousand.

12/ Any regulated person who, directly or indirectly, gives, offers, or promises any financial, in-kind, or any gift to any health professional with the intent to cause the health professional to prescribe medicine, medical device, or related product shall be punishable with imprisonment from three years to seven years and a fine from Birr twenty thousand to Birr two hundred thousand.

d) where the crime defined under this sub-article (a) and (b) is committed negligently, it shall be punishable by imprisonment from six months to one year.

10/ Any person who commits the provision that requires health examination and health certificate of employees having direct contact with food preparation shall be punishable with imprisonment from six months to one year.

11) Where the inspector under (a) and (b) of this sub-article commits the crime, the appropriate anti-corruption provision shall be applicable.
13/ Any person who, with the intent to materially profit himself or another person, gives or cause another person to give blood shall be punishable by simple imprisonment not exceeding three years and with a fine not exceeding Birr fifty thousand. If the person commits this act as his daily engagement and benefit out of other peoples need, shall be punishable by imprisonment from three years to ten years, and with a fine from Birr ten thousand to Birr one hundred thousand.

14/ Any person who violates the provision regarding blood and blood products and sub-standardizes the collection, testing, processing, screening, pooling and irradiation of blood and blood products shall be punishable with imprisonment not exceeding one year and a fine from Birr twenty thousand to fifty thousand.

15/ Any person who in violation of this proclamation, conduct clinical trial without being authorized by the executive organ; perform any activity beyond the scope of the clinical trial protocol; use investigational medicine or medical device without authorization by the executive organ; or give...
unauthorized financial, in-kind or other comparable gifts to any person to participate in the clinical study shall be punishable with imprisonment from one year to ten years and a fine from Birr twenty thousand to Birr one hundred thousand.

16/ Any manufacturer, importer, exporter, or wholesaler with a registration certificate, with the exception of a person having one-time purchase permit, that sells medicine to unlicensed person shall be punishable with rigorous imprisonment from five years to seven years and a fine from Birr five thousand to Birr one hundred thousand.

17/ Any person who fails to report to the executive organ or regional health regulator any adverse event caused by medicine, medical devise, or other product as required under the law; fails to make periodic report; or falsify, conceal, deceive, or perform related activities in the report shall be punishable with simple imprisonment with not less than three months and a fine from Birr ten thousand to Birr fifty thousand.

18/ Any person who contravenes the provisions of this proclamation regarding prohibition or limitations on advertising, promotion, and sponsorship activities shall be punishable by imprisonment for not less than three months and a fine from Birr thirty thousand to Birr one hundred thousand.

19/ Any person who prepares, publishes, transmits, or in any way participates in illegal or unauthorized advertisement
Any person who sell tobacco products in prohibited places where tobacco smoke, use, or sell is prohibited shall be punishable with simple imprisonment not exceeding six months and a fine not exceeding Birr five thousand. Any person who smokes or use tobacco products in prohibited places shall be punishable with a fine not exceeding Birr one thousand.

Any person who sale alcohol in prohibited places shall be punishable with simple imprisonment not less than six months or a fine not exceeding Birr five thousand.

Any person in charge of public places, workplaces, and conveyances who violated the requirement to post the “no-smoking” notice along with its corresponding sign, or failed to take the required measures when smoking or tobacco use occurred in violation of the law shall be punishable with imprisonment not less than three months and with fine from Birr one thousand to Birr ten thousand.

or promotion as defined under this proclamation and other law issued to implement this proclamation shall be punishable by simple imprisonment not exceeding three years and with fine not less than Birr fifty thousand.
23/ Any person, who manufactures, imports, wholesale, distributes, stores, or in any way sales tobacco product with prohibited ingredient, any tobacco product which is illicit, shisha, or electronic nicotine delivery system or other related cigarette resembling technology product shall be punishable by simple imprisonment from three months to three years, and a fine from Birr one thousand to two hundred thousand.

24/ Any person, who sells, furnishes, or in anyways gives tobacco product or alcoholic product to a person under the age of 21 shall be punishable by imprisonment for not less than three months, or by a fine from Birr one thousand to three thousand.

25/ Any tobacco manufacturer, importer, wholesaler, or distributor who violates the provisions requiring disclosure of tobacco product content, furnishing of related information to the executive organ, and the provision which restricts tobacco industry interferences shall be punishable with imprisonment from one year to three years, and fine not less than Birr fifty thousand.

26/ When any crime defined under this proclamation is committed by a legal entity, the court may as appropriate, may order the closure, suspension, or dissolving of the entity.
68. Handling and disposal of products

1/ The handling of any regulated product under this proclamation and that is expired, unusable, or unfit for use for any reason shall not be in a manner that could contaminate other products.

2/ Any product that is segregated in accordance with sub-article (1) of this article shall be disposed with due care to the health of human, animal and the environment, and the cost shall be covered by its owner or another appropriate person.

3/ The executive organ or regional health regulator, upon request by the appropriate person, shall give the necessary information regarding products disposed of in accordance with this provision.

69. Information handling

1/ Every manufacturer, importer, distributor, or retailer of a regulated product under this proclamation shall have a system that enables to show the condition and process of its distribution chain until it reaches the end consumer.

2/ Every manufacturer, importer, or distributor of a regulated product under this proclamation shall have the responsibility to handle, report, and furnish, upon request, to the executive organ or regional health regulator any information regarding the quality, safety, effectiveness of the product, and other related matters.
70. **Repeal and inapplicable laws**

1/ With respect to matters provided for by this Proclamation, Proclamation No. 661/2009 is hereby repealed.

2/ Article 8(5) of Proclamation No. 759/2012 is hereby repealed.

3/ 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.

71. **Power to issue implementing laws**

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

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

72. **Transferred power and responsibilities**

1/ Regulatory functions under Articles 3(2) (c), 3(2) (e), 4(2), 4(16), 46 and 47 of Proclamation No. 661/2009 which deals with registration and licensing of insufficiently available health professionals, the issuance of a certificate of competence and regulation of special health institution, and professional and premise license for traditional medicine and alternative and complementary medicine shall be performed by regional health regulators.
2/ Regulatory functions under Articles 3(2)(g), 4(14), and 4(15) of Proclamation No. 661/2009 which deals with quarantine and regulation of communicable disease at ports of entry and exits shall be performed by the Ethiopian Public Health Institute.

3/ Regulatory functions under Articles 3(2)(d), 3(2)(h), and 4(21) of Proclamation No. 661/2009 which deals with enforcement of hygiene and environmental health requirements by federal government owned health-related controllable institutions and trans-regional health-related institutions shall be performed by the Ministry.

4/ The Ministry shall monitor compliance with legal requirements by health institutions owned by the federal government.

5/ Articles 45 of Proclamation No. 661/2009 which deals with registration of traditional medicine and alternative and complementary medicine shall be carried out by the executive organ.

73. Provisional clause
The Health Professional Ethics Committee established by the Council of Ministers Regulation No. 299/2013 shall remain operational until such time another body is established by law to take over its responsibility, and regulatory functions under Articles 3(2)(d) and 4(16) of Proclamation No. 661/2009 which deals with registration and licensing of alternative and complementary medicine practitioners and other health professionals coming from abroad shall be performed by the Ministry.
1. This Proclamation shall enter into force on the
date of publication in the Federal Negarit Gazette.

2. Notwithstanding to sub-article (1) of this article,
article 53 (3), (5) and (7) of this proclamation
requiring labeling of medicine and medical
device to be in Amharic and English, requiring
barcode and placing of retail price requirement
shall come into effect at the eighteenth month
from the date of adoption of this proclamation.

3. Notwithstanding to sub-article (1) of this article,
article 57 sub-articles (1-3) regarding health
warning and packaging on tobacco products shall
come into effect at the twelve month from the
date of adoption of this proclamation.

4. Notwithstanding to sub-article (1) of this article,
article 55 of this proclamation
requiring health warning on alcohol products
shall come into effect after six months, and
article 60 banning the advertisement of alcohol
through broadcast and billboard shall come
into effect after three months from the date
of adoption of this proclamation the 5th day
of February 2019.

Dane at Addis Ababa on this 28th day of February 2019

SAHLEWORK ZEWDE

PRESIDENT OF THE FEDERAL DEMOCRATIC
REPUBLIC OF ETHIOPIA