EFDERAL NEGARIT GAZETA

OF THE FEDERAL DEMOCARTIC REPUBLIC OF ETHIOPIA

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CONTENTS

PROCLAMATION NO. 176/1999
A PROCLAMATION TO PROVIDE FOR DRUG ADMINISTRATION AND CONTROL

WHEREAS, realizing the significant role of health in securing proper life and productivity of the people and recognizing that drug shares a vital role in the health service, as well as in animal fertility and productivity and economic development of the country;

WHEREAS, it is found necessary to ensure the safety, efficacy and quality of drug and so to maintain the proper production, distribution and use;

WHEREAS, it is found necessary to deter the illicit production, traffic and use of narcotic drugs and psychotropic substances;

WHEREAS, to achieve these ends, it is found necessary to establish an effective system of drug administration and control'

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

PART ONE
General

1. *Short Title*

This Proclamation may be cited as the "Drug Adminis-tration and Control Proclamation No. 176/1999

2. *Definitions*

In this Proclamation, unless the context provides otherwise:

0. "Drug" means any substance or mixture of substances used in the diagnosis, treatment, mitigation or prevention of a disease in man or animal. This shall include narcotic drugs and psychotropic substances, pesticides, animal food additives, poisons, blood and blood products, vaccine, sera, radio active pharmaceuticals, cosmetics and sanitary items, medical instruments and medical supplies;

1. "Narcotic Drug" means any drug subject to control according to Narcotic Drugs Conventions of the United Nations ratified by Ethiopia. This shall also include a drug that is categorized as narcotic drug by the Authority;

2. " Psychotropic Substance" means any substance subject to control according to psychotropic Substances Convention of the United Nations ratified by Ethiopia. This shall also include a substance that is categorized as psychotropic substance by the authority;

3. "Poison" means any substance that may cause danger to man, animal, plant and environment when taken in a small quantity;

4. "Pesticide" means any chemical, mixture, compound or living organism used to prevent, control or destroy pests;

5. "Cosmetic" means any preparation intended to be applied to the human body for cleansing, beau tying, promoting attractiveness or altering the appearance without affecting the body's structure or functions. this includes products such as skin creams, lotions, perfumes, lipsticks, finger nail polishes, eye and facial makeup preparations, shampoos, permanent waves, hair colors, deodorant, medicated soaps and any ingredient intended for preparing these products;

6. "Sanitary item" means any preparation used in the maintenance of cleanliness of man, animal and household. This includes pads, tampons, dentifrices, sweat-bands, detergents;

7. "Medical Instrument" means any instrument that may be used on the innner or outer part of the body for diagnosis or treatment of a disease in man or animal. this includes various diagnostic, laboratory, surgery & dental medical instruments;

8. "Medical supply" means any article that may be used on the inner or outer part of the body for diagnosis or treatment of a disease in man or animal. this includes, suturing materials, syringes & needles, bandages, gauze, cotton & other similar articles, artificial teeth, chemicals and x-ray films;

9. "Drug Trade" means production, import, export, wholesale and retail of drugs. This shall include performance of quality control, establish and ran scientific offices and act as a commission agent,

10. "Certificate of competence" means a certificate showing the fulfillment of organizational requirements and preparedness by a person to carry out drug trade;

11. "Packing Material" means any article that may be used for filling, inserting or wrapping or packing drugs; and this includes immediate container and other materials for wrapping the immediate container;

12. "Label" means any material which is printed or affixed to a packing material which provides the necessary information about a drug and this includes an insert;

13. "Counterfeiting" means using in any way, the packing material or identification or any trademark, trade name or any special mark thereon of an authentic product of a manufacturer without the permission of the manufacturer and presenting such falsely labeled and packed drug as if it is manufactured by the genuine manufacturer.

14. "Adulteration" means reducing the quality of a drug by adding to its content a substance other than its content, or by substituting its content in whole or in part by such other substance, or by storing or manufacturing it under unsanitary conditions whereby it may have been contaminated with any other foreign matter;

15. "Clinical Trial" means testing a drug on human or animal subjects to prove its efficacy and safety.

16. "Pharmacy Personnel" means a pharmacist, druggist or pharmacy technician and it also includes veterinary health personnel;

17. "Veterinary Health Personnel" means a person trained in veterinary medicine, that enables him/her to carry out his/her profession, at a Degree, Diploma or Certificate level.

18. "Medical Practitioner" means a medical doctor, surgeon veterinarian or other health personnel who is licensed to Examine and diagnose the disease of humans or animals and treat them by drug or surgical operations;

19. "Prescription" means any order for drug written or signed by a duly licensed or authorized medical practitioner issued to a patient in order to collect drug from dispensing unit;

20. "Animals" means domestic and wild animals and also include sea animals and bees.

21. "Person" means any physical or juridical person.

PART TWO
Establishment of Drug Administration and Control Authority

3. *Establishment*

1) The Drug Administration and Control Authority, hereinafter referred to as "the Authority" is hereby established by this proclamation.
2) the Authority shall be accountable to the Prime Minister.

4. *Head Office*

The head office of the Authority shall be in Addis Ababa and it may have branch offices elsewhere as necessary

5. Objectives

The objective of the Authority shall be to ensure the safety, efficacy, quality and proper use of drugs.

6. Powers and duties of the Authority

The Authority shall have the powers and duties to:

1) Set standards of quality, safety and efficacy of drugs and ensure their observance;
2) Set standards of competence for organizations to be involved in drug trade. It shall issue a certificate of competence, control compliance with the standards, renew, suspend, and revoke the certificate of competence; and inform same to the concerned authority;
3) Prepare list of drugs for the country, structure the drugs in the list into different categories, revise the list whenever necessary;
4) Formulate policy governing the sector; prepare draft legislation and present it for the approval of the government;
5) Create favorable conditions for the promotion and expansion of drug trade and shall encourage and provide support to those who are involved in the trade;
6) Control the quality of raw materials and packing materials used for the production of drugs;
7) Monitor domestic or foreign new scientific achievements in the drug sector in order to adapt them to the country's condition thereby promoting and strengthening the sector;
8) Prepare standards of safety, efficacy and quality of traditional medicines; and shall evaluate laboratory and clinical studies in order to ensure the safety, efficacy and quality of traditional medicine; it shall issue license in order to use traditional medicine in the health service;
9) Serve as Drug Information Center and control drug information to be distributed to professionals and the public; it shall also disseminate current and unbiased information;
10) Make follow-up on domestic and foreign new scientific achievements on drug sector and shall put maximum effort for their implementation so as to promote and expand the sector;
11) Issue license for conducting clinical trial; monitor the process; evaluate the results and authorize the use of the result in such a way that it benefits the country;
12) Identify ingredients that caused death or ill health due to dry poisoning and forward possible remedies by conducting investigation on sample ingredients;
13) Organize quality control laboratory needed to carry out its duty;
14) Collect service fee;
15) Own property, enter into contracts, sue and be sued in its own name;
16) Perform other lawful activities as may be necessary for the attainment of its objective.

7. *Organization of the Athority*

The Authority shall have:

1. A Board,
2. A General Manager and Deputy General Manager,
3. The necessary staff

8. *Members of the Board*

The Board shall have seven members to be appointed by the government

9. *Powers and Duties of the Board*

The Board shall have the powers and duties to:

1. Direct and supervise the Authority;
2. Approve standards of safety, efficacy and quality of drugs;
3. Approve the list of drugs for the country;
4. Decide on complaints raised in the implementation of this proclamation;
5. Approve the plan of action and budget of the Authority and also ensure its implementation

10. Meetings of the Board

1. The Board shall meet once in three months and on such occasions as the chairperson may decide.
2. There shall be a quorum where the majority of the members of the Board are present.
3. Decisions of the Board shall be passed by majority vote and in case of a tie the chairperson shall have a casting vote.
4. Without prejudice to the provisions of this Article, the Board may issue its own rules of procedures

11. General Manager of the Authority

1) The General Manager of the Authority shall be appointed by the government upon recommendation of the Board.
2) The General Manager shall be the chief executive officer of the Authority and shall direct and administer the activities of the Authority.
3) Without prejudice to the general provisions of Sub Article (1) of this Article the General Manager shall:
   e) Exercise the powers and duties of the Authority specified under Article 6 of this Proclamation:
   f) Employ and administer personnel of the Authority following the basic principles of the federal civil service laws;
   g) Prepare and summit to the Board the annual plan and budget of the Authority and implement same upon approval;
   h) Effect payments in accordance with the approved budget and work program's of the Authority;
   e) Represent the Authority in all its dealings with third parties

f) Submit periodical reports to the Board.

4) The General Manager may delegate part of his powers and duties to the Deputy General Manager and employees of the Authority to the extent necessary for the efficient performance of its activities

12. *Budget*

The budget of the Authority shall be drawn from the following sources:

1) Budget allocated by the Government,
2) License/service fees, and
3) Any other source

13. Books of Accounts

1. The authority shall keep complete and accurate books of accounts.
2. The books of accounts and other financial documents of the Authority shall be audited annually by the Auditor General or by an auditor designated by him

14. *Inspectors*

1) The Authority shall assign pharmacy personnel as inspectors to ensure the implementation of this proclamation, and regulations and directives to be issued pursuant to this Proclamation.
2) An Inspector assigned pursuant to Sub Article (1) of this Article shall have the power and duty to:
   (a) Enter and inspect establishments for production, import, wholesale, and retail trade of a drug, health institutions and port of entry or exist at any opening hours;
   (b) Investigate and, if necessary, retain a photocopy of records, documents, prescriptions and the like pertaining to drugs;
   (c) Take samples of drugs produced locally or imported as evidence; in accordance with the sampling procedures that shall be formulated by the Authority;
   (d) Subject to quality control drugs that are adulterated, spoiled, counterfeit, contaminated or those suspected to be dangerous to the public, he shall be authorized to order the quarantine of such items until the results of the laboratory are known
   (e) Ensure the disposal of drugs when they expire or when they are deemed to be unfit for use in accordance with this Proclamation, and cause that decision be given within thirty days upon those under quarantine pursuant to Sub Article (2) (d) of this article

15. *Delegation of Powers and Duties*

The authority may delegate part of its powers and duties to regional legal bodies to the extent and whenever it deemed necessary for the efficient performances of its activities

PART THREE
Drug Registration and Control

16. Registration

1. No drug, whether produced locally or imported, shall be put into use unless it is duly registered by the Authority.
2. The registration shall be effected in accordance with the regulations to be issued for the implementation of this Proclamation.

17. Certificate of Registration

1) A registration certificate which remains valid for five (5) years shall be granted for a drug registered pursuant to Article 16 of this Proclamation.
2) The certificate shall show whether the drug is a prescription-drug or non-prescription drug; and also the level of the health institution or drug retail outlet where it shall be available

18. *Re-registration*

1) Any registered drug shall be presented for re-registration at least 120 days prior to the end of the validity date of the registration certificate.
2) The Authority shall issue detailed guidelines regarding the documents that should accompany an application for re-registration

19. Standard of Quality

1. The Authority shall assure the quality of drugs as per its own pharmacopoeia or the pharmacopoeia of other countries which are recognized by it.
2. No drug, raw material or packaging material which fails to comply with its quality specifications shall be put into use

20. Post Marketing Surveillance

1) The Authority shall carry out post marketing surveillance in order to ensure the safety, efficacy and quality of drugs that are put into use.

2) The Authority shall have the power to ban the use, or to revoke the registration, of a drug that was put into use when, later on, it is proved to be ineffective or its risk outweighs its benefit

21. Clinical Trial

1) A clinical trial shall be conducted only on a human being who has given his consent in writing and on domestic animals with the consent of the owner and on wild and sea animals when permission of the Government is obtained, and all of which are subject to the authorization of the Authority in accordance with the regulations issued for the implementation of this proclamation

1) Notwithstanding Sub Article (1) of this Article, a clinical trial shall not be conducted on nursing and pregnant women, on children under the age of 18 on prisoners, on insane persons, and on persons dependent on the investigator or on the institution.
2) No clinical trial result which has not been evaluated and approved by the Authority shall be published or disseminated in any way.
3) Any identifying data about the trial subjects shall be kept confidential

22. Dissemination of Information and Advertisement

1) No person shall disseminate any drug related information that is meant for professionals and the public unless after their usefulness and correctness is verified and approved by the authority.
2) No person shall cause advertisement concerning drug whether in writing or in any way which is not in compliance with law of trade advertisement, or the directives issued by the Authority, or which is misleading to the public as to their value or effect

23. Packaging Materials and Label

1) No drug shall be put on the market or distributed by any means unless it is duly packed or labeled as may be provided in the regulations and directives that may be issued to enforce this Proclamation.
2) Any drug manufacturer, importer, wholesaler, retailer or health institution shall ensure that all drugs which he offers for use are duly packed and labeled

PART FOUR
Narcotic Drugs and Psychotropic Substances

24. Special License Requisite

1) A special license issued by the Authority shall be required to import, export, manufacture or distribute narcotic drugs.
2) A special license to import, export, manufacture, possess or store narcotic drugs psychotropic substances shall be issued only to persons having drug trade license shall be issued only to persons having drug trade license organizations

24. Import and Export

1) Any person having a permanent special license to import or export narcotic drugs or psychotropic substances shall apply for a special import or export permit for each consignment; such special permit shall be valid only for ninety (90) days.
2) No person shall import or export narcotic drugs or psychotropic substances through post office or by ship.
3) No person shall import or export narcotic drugs or psychotropic substances packing them with other drugs or articles.
4) Any person who imports or exports narcotic drugs or psychotropic substances shall comply with packaging guidelines issued by the Authority.

26. Prescriptions

1) Only a medical practitioner who is registered and have a special license shall prescribe narcotic drugs.
2) Psychotropic substances shall be prescribed by a licensed and registered medical practitioner.
3) No medical practitioner shall prescribe narcotic drugs and psychotropic substances for himself.
4) Narcotic drugs and psychotropic substances shall only be prescribed on a special prescription paper.
5) The management of and standard that any prescription for narcotic drugs or psychotropic substances shall fulfill would be set forth in the regulation to be issued pursuant to this Proclamation

34. Storage

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

35. Disposal

Any person shall keep damaged, expired, or seized narcotic drugs or psychotropic substances in a separate place and shall dispose them in accordance with the directive to be issued by the Authority pursuant to this Proclamation

36. Cessation of Business

Any person who is licensed pursuant to this Proclamation and who ceases to operate his business shall deal with the stocks of narcotic drugs, psychotropic substances, invoices, other documents, and prescriptions related to same as directed by the Authority

37. Recording and Reporting

Any person who is licensed pursuant to this Proclamation shall keep records and send reports about narcotic drugs or psychotropic substances in accordance with a directive that shall be issued by the Authority

PART FIVE
Poisons and Radio pharmaceuticals

31. Poisons

1) The Authority, based on international standards, shall prepare a list of poisons and communicate to all concerned bodies, and issue a detailed directive on their storage, sale and disposal.
2) No person shall manufacture, import and distribute poisons unless he first have obtained a special permit from the Authority.
3) Any person who manufactures, imports or distributes poisons, shall keep detailed records of such poisons in accordance with the directives that may be issued by the Authority and reports to same.

38. Radio pharmaceuticals

1) The Authority shall issue regulations and directives regarding the storage, distribution, use and disposal of radio pharmaceuticals in accordance with the recommendations that it may receive from the International Atomic Energy Agency.
2) No person shall manufacture, import, distribute or sell radio pharmaceuticals unless he first have obtained a special permit from the Authority.
3) Any person who has a special permit pursuant to this Proclamation shall keep records and send reports of manufactured, imported or distributed radio pharmaceuticals, in accordance with the directives that may be issued by the Authority

PART SIX
Offenses

39. Illegal Drug Trade

Except penalizing in accordance with the penal code is stronger than the following:

1) Any licensed person who:
   a) Impedes the work of inspector assigned pursuant to Article 14 of this Proclamation shall be punishable with imprisonment for not more than six months or with a fine not exceeding ten thousand Birr or with both.
   b) Transfers the licenses issued to him to any person by way of any means shall be punishable with imprisonment of not less than one year and not more than three years and a fine of not less than five thousand Birr and not exceeding twenty thousand Birr.
2. Any licensed drug manufacturer, importer, exporter or wholesaler who sales drug to a person without a license shall be punishable with imprisonment of not less than two years and not exceeding five years and with a fine of not less than five thousand Birr and not exceeding twenty thousand Birr.
3. Any person who trades drug without a certificate of competence shall be punishable with imprisonment for not less than five years and not exceeding seven years and with a fine of not less than twenty thousand Birr and not exceeding fifty thousand Birr
4. Any licensed drug retailer who wholesales, or dispenses drugs in excess or less quantity than that justified by medical practice or purchase drugs from a person who is not licensed pursuant to this proclamation shall be punishable with imprisonment of not less than two years and not exceeding five years and with a fine of not less than five thousand Birr and not exceeding twenty thousand Birr.
5. Any person exercising unfair trade practice by counterfeiting, or adulterating or affixing or enclosing mislabel to packaging material, or buying or selling substandard or expired drugs shall be punishable with imprisonment of not less than ten years and not exceeding twenty years and with a fine of not less than twenty thousand Birr and not exceeding fifty thousand Birr.
6. Any person who fails to comply with the provisions of this Proclamation, or regulations and directives issued pursuant to this Proclamation, shall be punishable with imprisonment of not exceeding two years and with a fine of not exceeding ten thousand Birr
7. For the execution of this Article drug shall mean any substance excluding narcotic drugs and psychotropic substances

34. Offenses Facilitating Abuse of Narcotic Drugs and Psychotropic Substances

Any person who:

1) By way of any means, publishes or displays, or causes or permits to be published or displayed and any thing promoting or encouraging the abuse of narcotic drugs or psychotropic substances;
2) Is owner or occupier of a house, a compound or any place, causes or permits there the abuse of narcotic drugs or psychotropic substances;
3) Administers or causes or permits to be administered narcotic drugs or psychotropic substances without having a license to prescribe;
4) Without sufficient reason or above the standard dose, prescribes narcotic drugs or psychotropic substances, even if he has a license;
5) Sells or supplies narcotic drugs or psychotropic substances on presentation of a prescription, where he knows that the presentation is forged, unlawfully altered, cancelled or expired, shall be punishable with imprisonment of not less than 7 years and not exceeding 15 years and with a fine of not less than thirty thousand Birr and not exceeding fifty thousand Birr.

35. Confiscation

All properties used to or derived from the Commission of the offenses mentioned in Articles 33 and 34 of this Proclamation shall be confiscated

36. Other offenses Related to Drug

1) Any civil servant or official assigned to perform duties related to Drug Administration and Control activities who by taking bribes or through nepotism or favoritism or other illegal relationships by violating the Proclamation and regulations to be issued pursuant to this Proclamation;
   a) Issues and renews a certificate of drug trade competence and certificate of professional registration or mislead others to do so;
   b) Authorizes the use of drugs and raw materials without making adequate evaluation or investigation of their quality, safety and efficacy or mislead others to do so;
   Shall be punished with imprisonment of not less than ten years and not exceeding fifteen years and with a fine not less than Birr thirty thousand and not exceeding Birr fifty thousand.

2) The penalty provided for under Sub Article (1) of this Article shall also be applicable to person who has given bribe.
3) When the offense provided for under Sub-Article (1) of this Article is committed by more than one person, if one of them first give adequate information on the commission of the offense and the role of the major role player(s) before the case was seen by court, Ministry of Justice may free the person from criminal liability.

PART SEVEN
Miscellaneous

37. Submission of Information

Legally delegated and authorized bodies should submit current report, regarding Drug Trade License they issued or renewed, to the Authority.

38. Transitory Provision

The certificate of competence issued prior to the coming into force of this Proclamation shall be deemed to have been issued under this Proclamation and be subject to the provisions of this Proclamation and to regulations and directives issued pursuant to this proclamation.

39. Prohibition

Running Drug trade in the absence of a professional Pharmacy Personnel shall be prohibited

40. *Repea*l

1) The following are here by repealed:
   a) Decree No. 9/1947 relating to the Pharmacopoeia for the Maintenance and Administration of Medicine.
   b) The Pharmacy Regulations Legal Notice No. 288/64, with respect to matters covered in this Proclamation.
2) Any law, regulations, directives or practices which are inconsistent with the provisions of this Proclamation shall not apply with respect to matters provided for in this Proclamation

41. Powers to Issue Regulations and Directives

1) The council of Ministers shall issue regulations necessary for the effective implementation of this Proclamation.
2) The Authority shall issue directives necessary for the effective implementation of this Proclamation

42. *Effective Date*

This Proclamation shall enter into force as of the 29th day of June, 1999

Done at Addis Ababa this 29th day of June, 1999

NEGASO GIDADA (DR.)
PRESIDENT OF THE FEDERAL
DEMOCRATIC REPUBLIC OF ETHIOPIA