In the Name of Allah, the Gracious, the Merciful

The Drugs and Poisons Act, 2009

Arrangement of Sections

Chapter I

Preliminary Provisions

Section :-

Chapter II

The Board

Chapter III

Pharmaceutical Facilities

Chapter IV

Restriction of conducting Experiments

Chapter V

Poisons

Chapter VI

Miscellaneous Provisions

Chapter VII

Financial Provisions

Chapter VIII

Final Provisions

In the Name of Allah, the Gracious, the Merciful

The Drugs and Poisons Act, 2009

(31/5/2009

Chapter I

Preliminary Provisions

Title

1. **This Act may be cited as the, "Drugs and Poisons Act, 2009".**

Repeal and saving

2. **The Pharmacy and Poisons Act, 2001 shall be repealed; provided that all regulations, orders, licences and registrations made thereunder shall remain in force, until revoked, or amended, in accordance with the provisions of this Act.**

Interpretation

3. **In this Act, unless the context otherwise requires, :-**

"Adulterated drug",	**means the drug or pharmaceutical preparation or medical requisite or cosmetic preparation produced intentionally or fraudulently to contain less quantity of effective substance or no effective substances ;**
" Advertisement",	**means any attention drawing, publication, circular, label, poster, printed material, or statement issued in writing, or through any**

	means working by way of the issue, or transmission of sound , or light;
"Anesthetic drug",	**means any of the drugs and pharmaceutical preparations, or substances, set out in Part I, of the Poisons List, issued in accordance with the provisions of this Act;**
"Board",	**means the National Drugs and Poisons Board, established under the provisions of section 4(1);**
"Code drugs, or code pharmaceutical preparations",	**means the drugs, and pharmaceutical preparations, set out in one of drugs codes, validated by the Board;**
"Cosmetic preparation",	**means any substance, or mixture of substances, the purpose of which is to be placed, by way of rubbing, pouring, ordinary spraying, or atomization, fumigation or any other means, upon the surface of the man body, or any part thereof, for the purpose of cleaning, beautifying, or perfuming him, or making him more attractive, protecting him, or changing his form, shape or scent , and there shall be excluded therefrom soap, drugs and pharmaceutical preparations;**

"Dispense",	**means dispensing a drug, upon a prescription issued by a physician, or veterinary surgeon, in compliance with such prescription;**
"Drug",	**means any substance , or mixture of substances, made, sold, offered for sale or presented for use in the treatment, tranquilizing, protection from, or diagnosis of a disease, or unnatural physical conditions or symptoms in man, or animals;**
"Drugs code",	**means the official reference , which contains the chemical, biological, physiological and pharmaceutical specifications of human, or veterinary drugs, and pharmaceutical preparations, set out therein, and validated by the Board;**
"Drugs factory",	**means the facility licensed to produce, arrange, compose, pack or wrap pharmaceutical preparations, or the drugs primary substances, or any drug at an industrial level, and also the other products, having connection; which are used in medical, or health purposes, intended for sale, or wholesale distribution;**

"Drugs information bureau",	**means the pharmaceutical facility, licensed to work as an information bureau for drugs, pharmaceutical preparations and drug chemicals, to inform members of the medical professions, and otherwise of those of competence, through supplying them with the necessary scientific information on drugs and pharmaceutical preparations, and the substances produced by drugs factories, by such mass media, as this Act and the regulations made thereunder may allow;**
"Drugs store",	**means the pharmaceutical facility, licensed to import, purchase or distribute the registered pharmaceutical preparations, and the substances necessary for preparing the medical prescriptions, drugs industries and medical requisites, by wholesale only;**
"Generic drug",	**means the drug, or the pharmaceutical preparation, which is not subject to intellectual property protection, and can be produced, without licence, from the inventor thereof;**

"Generic name",	**means the seientific, or world name, other than the trade name, by which the drug, or the pharmaceutical preparation is known, as the Board may specify;**
“Health authority”,	**means the body, to which the public health matter is entrusted in the state, or whoever it may authorize;**
“Medical experiments”,	**mean any experiments, or studies, including giving any drug, or pharmaceutical preparation directly for man, or animal, for the purpose of knowing the safety, effectiveness or health damages thereof to man and animals;**
"Medical requisite",	**means any appliance, instrument, machine, revealing substance or any similar thing, or part thereof, prepared for the purpose of use in the diagnosis, treatment, protection or lessening of the effects of disease, in man and animals, for the purpose of amendment of the skeleton of the body, or any of the functions thereof; on condition that effecting the required effect shall not depend upon chemical reaction, or metabolism inside the body, and the same includes the requisites, pertaining to rearing and increasing the produce of animals , and there shall be excluded, from the same, drugs and pharmaceutical**

	preparations ;"Minister", Means the Minister to be specified by the President of the Republic;
"Official register",	**means the register, the possession and use of which is in accordance with the provisions of this Act, and the regulations made thereunder;**
"Pesticide",	**means any substance, or mixture of substances, prepared for the destruction of insects, rodents and harmful plants and pests;**
"Pharmacy",	**means the pharmaceutical facility, licensed to sell human, veterinary drugs, and the registered pharmaceutical preparations, medical requisites, cosmetic preparations and despense the medical prescriptions, at a retail shop, directly, or indirectly;**
“Pharmaceutical facility”,	**means pharmacies, drugs stores, drugs and pharmaceutical preparations factories, drugs, or information bureaux, veterinary drugs, simple drugs sale shops or serums production laboratories or;**
"Pharmaceutical preparations",	**mean the products, or compounds, which contain, or are described, to contain a drug, one, or more substances having medical characteristics for the treatment of man, or animals, from diseases, or protection from the same, or used for any**

	other medical purpose, which have previously been prepared in a pharmaceutical form, for sale, or giving the same, to the public, for external, or internal use, or by way of injection, and there shall be deemed as such all the botanical and zoological preparations, one component of which is botanical , or from a botanical, or zoological origin, and the liquids and such prepared substances, prepared for purification , as may have not been mentioned in the drugs codes, and likewise such special nutritional products, as may not be used , save for medical purposes and cosmetic preparations having medical effect, as the Board may specify;
"Pharmacist",	**means any registered pharmacist, licensed to practise the profession of pharmacy, in accordance with the provisions of the Sudanese Medical Council Act;**
"Physician",	**means a physican, or a dentist having a licence to practise his profession, in this capacity, in the Sudan , in accordance with the provisions of the Sudanese Medical Council Act;**
"Prepare",	**means dispensing , preparation, or composition of a drug, upon a medical**

	prescription, issued by a physician, or veterinary surgeon;
"Poisons",	**mean any substance set out in the Poisons List, prepared in accordance with the Board's regulations, or orders;**
"Qualified person",	**means the person, who is professionally specialized in the industry and circulation of drugs and pharmaceutical preparations, in accordance with the regulations, made by the Board;**
"Reference laboratory",	**means the National Reference Laboratory validated by the Board, as reference laboratory for analysis in specific field or fields;**
"Registered drug, or registered pharmaceutical preparation",	**means any drug, or pharmaceutical preparation fully manufactured, including packing and wrapping, produced by a certain factory, which is registered in accordance with the provisions of this Act;**
"Technical committees",	**mean the Human Drugs Technical Committee, the Veterinary Drugs Technical Committee and any other technical committees, as the Board may form, under the provisions of this Act;**
"Technical Manager",	**means the pharmacist or veterinary surgeon, who manages the pharmaceutical**

	facility, and is in charge thereof technically;
"Trade name",	**means such name, as the manufacturer of the drug, or the pharmaceutical preparation, its producer or distributor may call the drug, or pharmaceutical preparation, pertaining thereto, to distinguish the same from the similar drugs and pharmaceutical preparations (competitive),**
“Veterinary authority”,	**means the authority , to which the matter of the animal wealth in the state, is entrusted, or whoever it may authorize;**
"Veterinary surgeon",	**means veterinary surgeon in possession of the licence to practise his profession, in this capacity, in accordance with the provisions of the Sudanese Veterinary Council Act;**
"Drug un identical to specifications",	**means drug, pharmaceutical preparation, medical requisite, or cosmetic preparation, which the concentration of effective substance, or substances is unidentical to its tag or drugs code validated by the Board.**

Chapter II

The Board

Establishment of the Board

4.(1) There shall be established a board, to be known as the, "National Drugs and Poisons Board", having corporate personality, perpetual succession, a common seal and the right to litigate in its own name.

(2) The seat of the Board shall be at the National Capital .

(3) The Board shall be subject to the supervision of the Minister.

Constitution and term of the Board

5. (1) The Board shall be constituted by a decision of the Council of Ministers, upon recommendation of the Minister, of a chairperson and a number of members from those possessed of experience and high competence; provided that the same shall include all the specializations having connection and the decision shall specify the emoluments of the Board chairperson and the members thereof.

(2) Membership of the Board shall continue for the period of five years, and members may be re-appointed.

Functions and powers of the Board

6.(1) The Board shall be the national authority competent to lay down specifications and safeguards pertaining to the operations of import manufacture, control, storage, pricing, transport and use of drugs, cosmetic preparations, all medical requisites and pharmaceutical preparations, according to the validated specifications .

(2) Without affecting the generality of the foregoing, the Board shall have competence as to the following, to :-

(a) Validate the reference laboratories , and lay down the bases, safeguards and conditions necessary to license drugs stores,

pharmaceutical laboratories, drugs factories, veterinary vaccines, serums and drugs information bureaux ;

(b) register drugs, pharmaceutical preparations, cosmetic preparations, medical requisites and poisons, and specify the conditions, pertaining to registration;

(c) lay down the systems, safeguards and conditions, necessary for practice by the pharmaceutical facility, of the work for which they are licensed, and continuence thereby, in practice of the work;

(d) lay down the systems , safeguards and conditions, necessary for management of pharmaceutical facilities;

(e) register foreign drugs, and medical requisites companies, or the branches, or validated agent thereof, as to such safeguards and conditions, as it may specify by a decision thereof;

(f) license the conduct of drugs experiments, upon man, or animals after satisfying, by the applicant for licence, of the conditions set out in section 22(2), and his compliance with all such conditions, safeguards and rules of organizing the conduct of medical experiments, upon man and animals, as the Board may specify;

(g) lay down the conditions pertaining to registration of drugs, pharmaceutical preparations, cosmetic preparations , and medical requisites and include giving due regard to the need, safety, effectiveness, price, quality and protection of the consumer, registration period and renewal of the same, and fees due for payment ;

(h) specify a certain type of drugs, or pharmaceutical preparations, and bind the store owner, or agent of the producing company, to

import the same, whenever it deems the necessity of presence of such drug or pharmaceutical preparation in the country;

(i) bind drugs factories inside the Sudan to produce any type of the produced drugs thereof as necessity may require;

(j) approve exportation of drugs and pharmaceutical preparation to outside the Sudan;

(k) lay down the bases and safeguards for keeping registers of drugs and pharmaceutical preparations, the incoming and isued out of the drugs store;

(l) organize operations of producing and monitering drugs , control the quality and distribution of the same;

(m) prepare a list of poisons, and publish the same, in the Gazette, and amend it, from time to time;

(n) form any ad hoc, or standing committees, to assist it in performance of the tasks thereof, and specify the functions of the same.

(o) Validate the co-ordination policies with bodies having connection;

(p) approve the organizational chart and scale of posts of the General Secretariate;

(q) any other powers, as may be necessary for implementation of the provisions of this Act.

(3) The Board may delegate any of the powers and functions thereof to the Chairperson, any of the members or committees of the same, as to such conditions as it may deem fit.

Meetings of the Board

7.(1) The Board shall convene, at least three times annually upon call of its Chairperson and the Chairperson of the Board may call for an emergent meeting, whenever he deems necessity therefor,or upon written request of two- thirds of the members of the Board.

(2) In case of absence of the Chairperson, the eldest of the member shall assume presidency of the Board .

(3) The quorum for meetings of the Board shall be constituted by the attendance of more than half the members thereof.

(4) Decisions of the Board shall be passed by majority of the members present; provided that the Chairperson of the Board shall have a casting vote, in case of equality of votes.

Disclosure of general interest

8. The Chairperson of the Board or any of its members having a direct, or indirect interest in any matter or proposal submitted before the Board for consideration thereof, shall disclose to the Board the nature of the interest which connects him to such matter, or proposal, and shall not participate in any deliberation, or decision passed by the Board with respect to the same .

Functions and powers of the Chairperson of the Board

9. The Chairperson of the Board shall have the following functions and powers , to :-

(a) preside the Board, call for meetings, thereof and specify the agenda of the meeting, in consultation with the Secretary General;

(b) supervise the performance of the General Secretariate of the Board;

(c) represent the Board, inside and outside the Sudan; and speak in its name;

(d) delegate any of his powers to any of the members;

(e) any other functions, as the Board may assign thereto.

The General Secretariate

10. The Board shall have a General secretariate, under the presidency of the Secretary General.

Appointment of the Secretary General

11.(1) A full-time Secretary General of the Board shall be appointed by a decision of the Council of Ministers, upon recommendation of the Minister and the decision shall specify his emoluments.

(2) The Secretary General shall be responsible for the performance of his duties, to the Board.

Functions of the Secretary General

12. The Secretary General shall have the following functions, to :-

(a) follow-up execution of the Board's decisions;

(b) assume the executive, administrative, technical and financial responsibility of the Board;

(c) prepare the agenda of the Board , under supervision of the Chairperson of the Board and keep correspondence relating to such business;

(d) keep minutes of the sittings and present the same to the members;

(e) send decisions of the Board and the recommendations thereof to the competent bodies, and notify the Board of what has been executed;

(f) keep the seal of the Board and use the same in such manner as the regulations may specify.

Constituion of Technical Committees

13.(1) The Board , by a decision thereof, shall constitute a human drugs committee, a veterinary drugs committee and any other technical committees, and shall specify the functions and tasks of the same, to help it in implementing the provisions of this Act.

(2) Such committees may make internal regulations to organize their business.

National Reference Laboratory

14.(1) The National Reference Laboratory shall be the Reference Laboratory, validated by the Board; and shall be subordinate thereto.

(2) There may be other validated laboratories, the specifications and conditions of which shall be laid down by the Board, and their certificates shall validated thereto.

(3) The Board shall validate the qualified persons who have the right to release the drugs and the pharmaceutical preparations locally manufactured, or imported at the National Reference Laboratory, or the other validated laboratories, as to such regulations, as the Board may make, and no certificate issued by such laboratories shall be validated save after signature thereof by the qualified person.

Chapter III

Pharanaceutual Facilities

Licences

15. No person shall manafacture, prepare, synthesize, import, distribute, sell, offer for sale, transfer or circulate any pharmaceutical preparation, or any of the poisons provided for int his Act, unless he is licensed therefor, in accordance with the provisions of this Act .

Registration of drugs and pharmaceutical preparation mandatory

16.(1) No person shall manufacture, prepare, synthesize, import, distribute, sell, or offer for sale, or deliver for resale any drug, or pharmaceutical preparation, medical requisite, or cosmetic preparation, save after registration thereof, in accordance with the provisions of this Act and the regulations made thereunder .

(2) There shall be excluded from the provisions of sub-section (1), such preparations, as may be prepared inside the pharmacy , and the approved samples, in accordance with the provisions of this Act, and procured for the purpose of registration, publicly, researches or emergency drugs, as the Board may prescribe .

Registration of drugs and pharmaceutical preparations rejected

17. The Board may reject the registration of any drug, pharmaceutical preparation, cosmetic preparation or medical requisite, or renewal of registration , whenever the same is convinced that such drug, or preparation does not satisfy the conditions of registration, at the

time of rejection, together with expressing the reasons in writing to the applicant .

Foreign drugs and pharmaceutical preparation companies listed in the register

18.(1) No drug, pharmaceutical preparation, cosmetic preparation or medical requisite shall be imported, from any company outside the Sudan, unless such company is listed into the registers of the Board.

(2) The Board shall verify the veracity of the data, presented by such companies, by all the means, and it shall have the right to monitor and inspect the factories and stores of such companies, for such purpose.

Conditions and requirements of registering foreign drugs and pharmaceutical preparations companies

19. In addition to any conditions, specified by the regulations concerning the registration of foreign drugs, pharmaceutical preparations, cosmetic preparations and medical requisites companies, the company shall produce :-

(a) what proves that it is the manufacturer of the drug, pharmaceutical preparation, medical requisite or cosmetic preparation, and not a packer thereof;

(b) what proves that the products thereof are allowed to be circulated in the country of origin, with the same composition, type and requirements of use;

(c) a statement of the branches of the same, together with specifying the form and activity of each branch thereof, be it a manufacturer, packer or distributor;

(d) a statement of the names of drugs, pharmaceutical preparations medical requisites and cosmetic preparations it manufactures;

(e) the date of establishment thereof, and the names of the states in which it is registered.

Certificate of registration

20. The Board shall issue a certificate of registration of the drug, pharmaceutical preparation, cosmetic preparation or medical requisite in the prescribed form, for a period of five years, and the same includes any prescribed restrictions , after payment of the prescribed registration, or renewal fees; and in case of non-renewal, the registration shall be deemed as automatically revoked .

Appeal

21.(1) Any person aggrieved by any decision, issued by any of the technical committees or the authorized committees, may appeal, to the Board, within fifteen days, of the date of the decision, and the decision of the Board, in this respect, shall be final.

(2) Any person aggrieved by any decision passed by the Board, under the provisions of this Act , may appeal, to the competent court, within fifteen days, of the date of his being notified of the decision.

Chapter IV

Restriction of Conducting Experiments

Approval of conducting experiments on human beings

22.(1) No person shall conduct medical experiments of any drug, or pharmaceutical preparation, on any human being , save upon approval of the Board.

(2) For obtaining the licence, the following shall be produced :-

(a) a scientific instrument showing all the details of the experiments which he intends to conduct;

(b) sufficient details of the drug, or pharmaceutical preparation, to be experimented and given to humans beings, the dosages, quantities, the manner of taking thereof, and the type and the number of examinations, and analysises intended to be conducted on human beings, and the number, the type and age of the persons, upon whom the experiments are to be conducted;

(c) constituents, toxities, physiological, biological and clinical effect of the drug, or pharmaceutical preparation, on the body and functions thereof, and all such as may relate to the effectiveness, effects and safety of the same on the human being, and details of the previous experiments;

(d) any other data and information, as the Board may prescribe in the regulations.

Conduct of experiments not allowed

23. No licence, or allowing the conduct of any medical experiments on human beings shall be made unless the results of the previous authenticated scientific and medical experiments, which have been conducted in other states, prove the non-damage, by the drug, or pharmaceutical preparation concerned, to the human health, in comparison with the alternatives in

use, together with taking in consideration the effectiveness of the drug, or preparation and type of disease.

Consent of the person concerned to conducting experiments

24. **No experiment shall be conducted on any person, unless he produces his consent in writing, and validated by the health authority, after being informed, or after informing his guardian, in case of a minor, with every clarity that medical experiments are to be conducted thereon, and his being enlightened of all the harmful effects, as may result from the experiments of using the drug, or preparation, and the number and types of samples, to be taken from him, and the examinations and analysises to be conducted thereon, and the securities and rights, to be provided for him.**

Experiments conducted on animals

25. **No experiments, pertaining to medicines, drugs and pharamaceutical and veterinary preparations shall clinically be conducted on animals, save after obtaining a permit therefor, from the Board, in accordance with the regulations.**

Responsibility of the body which requested the conduct of experiment

26. **The person, or body, who requests the conduct of experiment , shall directly and fully be deemed responsible for any damages occurring to man , the society or environment, as a result of conduct of the experiment, and be bound to pay all the rights and compensations resulting from such damages, in addition to any other legal responsibility.**

Chapter V

Poisons

List of poisonous substances

27.(1) The Board, by an order therefrom, shall issue a list of such substances as may be deemed poisons, in accordance with the provisions of this Act, and shall publish the same in the Gazette,e and it may amend such list, from time to time, as it may deem fit.

(2) The list, issued under the provisions of sub-section (1) , shall be divided into three parts, as follows, :-

(a)Part I, and includes anesthetic substances used in drugs, and the Board deems to be one of the dangerous anesthetic substances, which may lead to addiction, subject to the provisions of the Narcotics and Psychotropics Act, 1994.

(b) Part II, and includes such poisons, as may, in the Board's opinion, be undangerous drugs; provided that they shall be dispensed by a registered pharmacist, or a person licensed to sell the poisons set out in Part II;

(c) Part III, and includes the poisons other than drugs, which are in common use by the public, for purposes not relating to the treatment of man, or animals .

(3) The Board may make the necessary orders to lay down the safeguards and bases, relating to paragraphs (b) and (c); provided that such safeguards shall include the dispensing of poisons and the medical

prescription, the manner of enlisting data, and denoting the same in such register, as may be kept for this purpose .

Pesticides deemed poisonous substances

28.(1) For the purposes of this Chapter, all pesticides shall be deemed poisonous substances.

(2) No import, manufacture or circulation of any of the pesticides, registered under the provisions of the Pesticides Act, 1974, shall be made , save after the deposit of sufficient information, with the Board, on :-

(a) the chemical composition and the concentration of the same;

(b) the data, pertaining to the toxity of the pesticide to man and animals directly, or through pollution of water, soil and the nutritional products, by the remains thereof;

(c) the toxic effects resulting from misuse;

(d) the method of use of the pesticide, in such sound way, as may protect man and animals;

(e) the method of first aid and antidote.

Safeguards of the import, manufacture and dispensing of anesthetic drugs

29.(1) Subject to the provisions of the Narcotics and Psychotropics Act, 1994, no :-

(a) person shall import, manufacture or circulate any anesthetic drug, not set out in the Poisons List;

(b) pharmaceutical facility shall import, into the Sudan, or export therefrom, any anesthetic drug, save under a licence, issued by the Board in the prescribed form;

(c) pharmaceutical facility shall manufacture any anesthetic drug, or conduct any operation for prescribing the same, save under a special licence issued by the Board, in the prescribed form, and there shall be specified, in such licence, the place of work, and such conditions, as may have to be complied with to manufacture the anesthetic drug;

(d) pharmaceutical facility shall dispense, or obtain any anesthetic drug, to any other person not in possession of a licence, or not licensed in another way, to possess such anesthetic drug, or to any person having a licence, or licensed as aforesaid, save in accordance with the provisions and conditions of such licence.

(2) The provisions of sub-section (1) shall not apply, where the anesthetic drug has been dispensed, or prepared by a registered pharmacist himself, in a lawful way, in a licensed shop, in accordance with a medical prescription, issued by a physician, or veterinary surgeon, or given under the personal supervision of such physician, or veterinary surgeon.

The medical prescription for dispensing anesthetic drugs

30. Subject to the Narcotics and Psychotropics Act, 1994 , the Board shall specify, by regulations, to be made thereby, the conditions and safeguards of the issue of the medical prescription for dispensing anesthetic drugs, including the purposes for which dispensing is made, and the safeguards, relating to possession of anesthetic drugs, and the manner of keeping the record in the pharmaceutical facility shop.

Chapter VI

Miscellaneous Provisions

Advertisement of drugs and pharmaceutical preparations restricted

31.(1) **No person shall publish, or participate in the publication of any advertisement of any drug, or pharmaceutical preparation or medical requisite or herb or any substance purporting to be treatment or protection against a disease, whatever the type thereof, in such form, or way, as is intended to promote the use of the drug, or pharmaceutical preparation, for the treatment of, or protection against diseases, or diagnosing the same, or for the restitution, by man , or animals, of the physiological functions of the body thereof, unless he obtains the approval of the Board.**

(2) **The regulations shall specify the manner of advertisement, the contents, shape, form , period, preparation and the veracity of the contents thereof.**

Tag of drugs and pharmaceutical preparations

32.(1) **Every package, whether small, or large containing a quantity of any drug, or pharmaceutical preparation previously packed shall bear a tag, bearing the prescribed data in clear and legible letters.**

(2) **The regulations shall specify the matters, pertaining to placing the drugs and pharmaceutical preparations tag, and the contents, shape, and the cases wherein some packages may be excluded from the provisions of this section.**

(3) **Drugs freely distributed by the Government, or such as may come by way of grants, shall bear a clear tag showing the same.**

Generic names used

33. None of the public sector institutions, or any of the employees thereof shall use names, other the generic names of drugs and pharmaceutical preparations, upon prescribing, dispensing advertizing or dealing therein, in any of the ways.

Chapter VII

Financial Provisions

Financial resources of the Board

34. The financial resources of the Board shall consit of the following :-

(a) such appropriations, as the State may allocate thereto;

(b) such fees and funds, as may be collected in consideratin of such business, services or pieces of advice, as the Board and its General Secretariate or committees may render, upon approval of the Ministry of Finance and National Economy;

(c) such aids and gifts, as the Board may accept ;

(d) any other resources, as the Board may approve.

Accounts and audit

35.(1) The Board shall keep accurate and comprehensive books of accounts, as to such sound accountancy bases, as may be followed in this respect.

(2) The Board shall deposit its funds with banks, in current accounts, or as an investment deposit; provided that dealing in such accounts and withdrawal therefrom shall be as to such prescribed systems, as may be in use, in accordance with the Financial and Accountancy Procedure Act.

(3) The National Audit Chambers, or whoever it may authorize therefor, and under the supervision thereof, shall audit the accounts of the Board, after the end of every financial year.

Budget

36. The Board shall have an independent budget, to be prepared in accordance with bases in use in the State.

Chapter VIII

Final Provisions

Adulterated drugs and pharmaceutical preparations

37. Any drug, pharmaceutical preparation, medical requisite or cosmetic preparation shall be demmed as adulterated, where:-

(a) it has been produced internationally or fraudulently to contain less quantity of effective substance or substances.

(b) It does not contain any effective substance or substances.

(2) No adulterated drug, pharmaceutical preparation, medical requisite or cosmetic preparation shall be manufactured, imported, sold, offered for sale, distributed or circulated .

Pharmaceutical preparations unidentical to specifications

38.(1) Any drug, pharmaceutical preparation, medical requisite or cosmetic preparation shall be deemed to be unidentical to the specifications where it does not fulfill the conditions of the required specification.

(2) No drug, pharmaceutical preparation, medical requisite or cosmetic preparation shall be distributed, sold or offered for sale, where if it is

proved by laboratory analysis that it is not identical to the specifications.

Penalties

39. Subject to the provisions of paragraph (c) , and any severer penalty in any other law :-

(a) whoever contravenes the provisions of this Act, shall , upon conviction, be punished in accordance with the Schedule hereto;

(b) whoever contravenes the provisions of the orders, or regulations, made under the provisions of this Act, shall, upon conviction, be punished, with imprisonment, for a term, not exceeding five years, or with fine, or with both;

(c) the court, upon conviction under the provisions of any of paragraphs (a), or (b), may order the confiscation of any drug, pharmaceutical preparation, cosmetic preparation or medical requisite, where it is fit for use, or destroy the same, where it is unfit for use, upon request of the Board.

Power to make regulations

40. The Board may make such regulations, as may be necessary for implementation of the provisions of this Act. Without prejudice, to the generality of the foregoing, such regulations may provide for the following matters :-

(a) organizing, or restricting the registration, or renewal of registration of pharmaceutical preparations, cosmetic

preparations and medical requisites, or revocation of the registration of any one thereof;

(b) organizing the work of drugs information bereaux and laying down the safeguards necessary for the activity thereof ;

(c) the conditions, to be satisfied by pharmaceutical laboratiories, to secure the quality of production thereof, and control the same;

(d) excluding any commodity, substance, or group of commodities, or substances, into the composition of which, any drug, or any substance enters, from any of the provisions of this Act, as may be connected to sale of drugs;

(e) methods of preserving and storage of drugs;

(f) importing drugs, therapeutical substances, cosmetic preparations and medical requisites, and exporting, transport, possession, sale and placing tags thereon;

(g) adding particular elements to any drugs, or poisons, as may make the same easy to distinguish;

(h) laying down the bases and safeguards of manufacturing composition and preparation of drugs;

(i) the conditions, to be satisfied, upon registration of companies producing imported drugs and medical requisites;

(j) the rules of such sound practices, as compliance therewith may be mandatory, in the pharmaceutical facility, upon manufacture , preparation, storage,

transport, keeping, circulation and dispensing of drugs and pharmaceutical preparations;

(k) the conditions of circulation of medical herbs and the preparations, control of the manufacture, preparation, prescription and use thereof, for securing the safety, effectiveness, quality and the good use thereof;

(l) specifying the prescribed forms, registers and certificates;

(m) restriction of the circulation of the substances, which are poisonous, and harmful to health, for the control of circulation of which no other law provides, to protect man, animals and the environment, from the dangers thereof;

(n) the fees payable, for registration, licensing and appeal in accordance with the provisions of this Act;

The Schedule

(See section 39)

Contravention of sections	Penalties
37	**Imprisonment, for a term, not less than ten years, in addition to fine**
38	**Imprisonment, for a term not less than five years, in addition to fine.**
15, 22, 23, 28 , 29	**Imprisonment, for a term not exceeding five years, or with fine, or with both.**
24	**Imprisonment, for a term, of two years or fine, or both**
16, 18, 32	**Imprisonment for a term of one year or with fine or with both**
25, 31 , 33	**Imprisonment for a term, not exceeding six months, or with fine, or with both**