CHAPTER P1 - PATENT AND PROPRIETARY MEDICINES (CONTROL) LAW

ARRANGEMENT OF SECTIONS

SECTION

PATENT AND PROPRIETARY MEDICINES (CONTROL) LAW

A Law to provide for the licensing of vendors of patent and proprietary medicines.

[KWS 8 of 1990, No. 4 of 2006.]

[Date of commencement: 1*st April*, 1990]

1. Short title

This Law may be cited as the Patent and Proprietary Medicine (Control)

Law.*

2. Interpretation

In this Law unless the context otherwise requires—

"Commissioner" means the State Commissioner charged with responsibility for health matters;

"drug" means an article intended for use in diagnosis, cure, mitigation, treatment, or prevention of disease in man and animal but does not include native herbs;

"hospital" means a Government hospital;

"Inspector" means a Pharmaceutical inspector appointed in that behalf by the licensing authority;

"licensing authority" shall be such a person as the Commissioner shall prescribe but who shall be a registered pharmacist and not below the rank of a Deputy Director in the employment of Kwara State Ministry of Health;

"premises" means any place used for the retail and wholesale of medicines;

"State" means the Kwara State of Nigeria.

3. Licensing authority

The licensing authority shall be responsible for the issuance of licence in accordance with the provisions of this Law authorising the holder of the licence to carry on business as a patent and proprietary medicine vendor on the premises specified in the licence for the purposes of selling any medicines that shall be prescribed by the Commissioner from time to time.

4. Licensing of patent and proprietary medicines vendor

All patent and proprietary medicines vendors in the State shall be licensed before they can carry on business within the State.

5. Failure to licence as a vendor

(1) Any person who carries on business as a patent and proprietary medicines vendor without being licensed in respect thereof under this Law shall be guilty of an offence and liable on conviction to a fine not exceeding five thousand naira or to imprisonment for a period not exceeding five months or to both.

[No. 4 of 2006.]

(2) Any person who manages or assists in the management of a patent and proprietary medicine store which no person is licensed to manage shall be guilty of an offence and liable on conviction to a fine not exceeding five thousand naira or to imprisonment for a term not exceeding five months or to both.

[No. 4 of 2006.]

6. Making of false statement in application for licence

A person commits an offence if, for the purpose of—

(*a*) procuring the registration for himself or another person as a patent and proprietary medicines vendor; or

(*b*) procuring whether for himself or another person, the entry of any place as a registered premises for the sale of patent and proprietary medicines,

he makes any statement which he knows to be false.

7. Registration of premises

A person commits an offence if, being a registered patent and proprietary medicine vendor he has a place of business which is not entered in the register for the area in which the place of business is situated and carries

on business as a patent and proprietary medicines vendor at the place.

8. Failure to comply with registration conditions

Without prejudice to sections 6 and 7 of this Law, a person commits an offence if he fails to comply with any of the conditions of registration imposed on him by the licensing Authority.

9. Manner of application and fees payable

(1) Any application for the grant of a new licence or renewal of an old licence shall be made in such form and manner, and shall contain, or be accompanied by, such information, documents, samples and other materials as may be prescribed.

(2) The fees payable in respect of a licence issued under this section shall be as specified in the First Schedule hereto.

[First Schedule.]

(3) A licence granted under this Law shall be as in Form A of the Second Schedule hereto.

[Form A.]

10. Criteria for qualification and disqualification

Where an application is made to the licensing authority in accordance with section 9 and is accompanied among others with the prescribed fee and a report from the inspector, the licensing authority, if satisfied—

(*a*) that the premises is constructed and equipped to such standards as may be prescribed;

(*b*) that the applicant is a holder of at least a West African School Certificate or its equivalent;

(*c*) that the applicant is capable of complying with such conditions as may be imposed or attached to the licence;

and

(*d*) that the applicant is in all respects a suitable person to be granted a licence, subject to such conditions as may be imposed or as may be attached thereto, may grant a licence in such form as may be prescribed to the applicant in respect of the premises for which application is made.

11. Duration of licence and renewal

(1) Unless cancelled under section 13 of this Law, a licence shall remain in force up to the 31st of December of the year in which the licence is granted but may be renewed yearly on payment of the prescribed fees.

(2) When renewing a licence the licensing authority may vary the conditions attached to the licence and may impose additional conditions.

12. Power to vary or revoke any condition on licence

The licensing authority may, by an instrument in writing, vary or revoke at any time any condition for the time being attached to a licence, or direct that a registered premises be relocated.

13. Power to cancel a licence

(1) Where the licensing authority has reasonable grounds for believing that a registered premises is no longer fit to be used for the purpose for which it was intended or that the licensee has failed to comply with any regulations made under the provisions of this Law, the licensing authority may after giving the licensee the opportunity of being heard or making representations, by notice in writing require him before the date specified in the notice to remedy to the satisfaction of the licensing authority the defects in the notice.

(2) If the licensee fails to comply with the requirements of a notice under subsection (1) before the date specified therein, the licensing authority,

after calling upon the licensee to show cause why his licence should not be cancelled, may cancel the said licence and the premises shall be sealed off.

14. Exhibition of licence

(1) Every licensee shall exhibit the following in conspicuous places in his registered premises in which he carries on business as a patent and proprietary medicines vendor so as to be easily readable from outside the office—

(*a*) the original copy of his licence; and

(*b*) a notice of his name and the information that he is licensed as a patent and proprietary medicines vendor; or

(*c*) the name and style under which he is carrying on business as a patent and proprietary medicines vendor if the business is not being carried on in his own name.

(2) The information required by subsection (1) of this section to be specified in the notice referred to in that subsection shall also be clearly shown on all notices, and other publications issued by the licensee and in all letters, accounts, agreements and other documents sent out, entered into, or published by or on behalf of the licensee in or in the course of or in connection with his business as a patent and proprietary medicines vendor.

15. Production of licence

(1) A person to whom a licence under this Law is granted, shall, on being so required by any person authorised in writing for the purpose by licensing authority, produce the licence for examination.

(2) Where a licence granted under this Law expires or is revoked, then, if the holder of the licence fails to surrender it when called upon to do so, a person authorised by the licensing authority may require him to produce the licence, and upon its being produced, may seize it or deliver it to the licensing

authority.

(3) If a person who is required under subsection (1) or (2) of this section to produce his licence fails to do so, he shall be guilty of an offence, and liable on conviction to a fine of five thousand naira or to imprisonment for one month or to both such fine and term of imprisonment.

[No. 4 of 2006.]

16. Appeal against refusal variation suspension or cancellation of licence

Any person aggrieved by—

(*a*) the refusal of the licensing authority to grant or renew a licence; or

(*b*) the cancellation of a licence,

may within thirty days after receiving from the licensing authority notification of his decision, appeal to the Commissioner.

17. Appointment of Inspector and functions

(1) The Commissioner may appoint such number of persons to serve as Inspectors for
the purpose of —

(*a*) carrying out any inspection as may be required under the provisions of this Law;

(*b*) supervising the enforcement of the provisions of this Law.

(2) Without prejudice to any other power conferred by this Law, an Inspector may—

(*a*) enter and inspect any premises occupied by any licensee;

(*b*) examine any books, accounts or other documents relating to the trade or business of any licensee;

(*c*) require any licensee to furnish any information in relation to his business;

(*d*) conduct on behalf of the Commissioner, any civil or criminal proceedings arising under this Law; or

(*e*) do any other thing necessary or expedient for the proper discharge of his functions.

(3) Any person who knowingly hinders, or obstructs any Inspector in the exercise of his duties, shall be guilty of an offence and liable on conviction to a fine of five thousand naira or to imprisonment for three months or to both such fine and imprisonment.

[No. 4 of 2006.]

18. Power to seal up premises

(1) Where an Inspector has reasonable grounds to believe that any premises has been, is being or will be used directly or indirectly for the purpose of frustrating the operation of this Law, he may seal up the premises in question.

(2) Where an Inspector acts under subsection (1) of this section, he shall report his action to the Commissioner for Health.

(3) Any person aggrieved by the action of the Inspector, may appeal to the Commissioner who may confirm or overrule the decision of the Inspector.

(4) A premises which is sealed up under this section shall remain sealed up until conditions for its reopening are complied with, or the Commissioner directs otherwise.

(5) Any person who knowingly and without reasonable excuse breaks a seal affixed pursuant to subsection (1) above, shall be guilty of an offence and liable on conviction to a fine not exceeding five thousand naira or to

imprisonment for a period of three months or to both such fine and imprisonment.

[No. 4 of 2006.]

(6) Where the sealing up of a premises takes place in addition to the trial of an offender under this Law, the premises shall remain sealed until the final determination of the case.

19. Inspection of medical product or container, etc.

For the purpose of ascertaining whether there is or has been a contravention of this Law or of any regulations made thereunder, an Inspector shall have a right to inspect any substance appearing to him to be a medicinal product, any article appearing to him to be a container or package used or intended to be used to contain any medicinal product and to seize and detain any substance or article which he has reasonable cause to believe to be a substance or article in relation to which an offence under the provisions of this Law has been committed.

20. Forms

The forms to be used in the implementation of the provisions of this Law shall be as contained in the Second Schedule hereto or such as may be prescribed by the Commissioner from time to time.

[Second Schedule.]

21. Sale of false and adulterated medicines

(1) No person shall label, package, treat, process, sell or advertise any medicinal product, cosmetics or device that is false or misleading, adulterated or is likely to create a wrong impression as to its quality, character, value, composition, merit or safety.

(2) A person found guilty of an offence under this section shall be liable to a fine of twenty thousand naira or to one year's imprisonment or to both such fine and term of imprisonment.

[No. 4 of 2006.]

(3) Where a person is convicted under this section, the medicine, cosmetics or devices on the basis of which he was convicted shall be liable to forfeiture.

22. Unlawful sale of medicine

No person shall sell or advertise for sale any medicine or medicinal preparations unless he is generally authorised so to do.

23. Transportation of medicines

A Pharmaceutical Inspector shall have the right to examine any consignment of drugs being transported within the State and for the purpose of analysis or examination thereof, to take samples of any such drugs.

24. Processing fees to be paid by pharmacists

(1) Every pharmacist whether carrying on business alone or as a partner in a firm or as an employee shall pay annually in respect of every address at which he carries on his business a processing fee at the rate specified in the First Schedule hereto.

[First Schedule.]

(2) This section shall not apply to any pharmacist in the service of a Government.

25. Other offences

Any person who contravenes any provisions of this Law where no punishment has been prescribed shall be guilty of an offence and liable on conviction to a fine of twenty thousand naira or to imprisonment for one year or to both such fine and imprisonment.

[No. 4 of 2006.]

26. Dispensing of psychoactive medicine

(1) Any person who dispenses any psychoactive medicine including those contained in the Third Schedule hereto without a prescription issued and duly signed by a qualified medical practitioner or any drug not on the approved Patent Proprietary Medicine Vendor List shall be guilty of an offence and liable on conviction to a fine of five thousand naira or to six months imprisonment.

[Third Schedule.]

[No. 4 of 2006.]

(2) No patent and proprietary medicine store shall stock or dispense any psychoactive medicine or any drug not on the approved Patent Proprietary Medicine Vendor List.

[No. 4 of 2006.]

(3) Any patent and proprietary medicine store that contravenes the provisions of subsection (2) shall be guilty of an offence and shall be liable on conviction to a fine of fifty thousand naira.

[No. 4 of 2006.]

27. Power to make regulations

The Commissioner may make regulations for the carrying out of the purpose and provisions of this Law, including the review of the lists of drugs and fees contained in the Schedule to this Law.

28. ……..

[No. 4 of 2006.]

FIRST SCHEDULE

[Sections 9 and 24.]

[No. 4 of 2006.]

Patent and Proprietary Medicines Vendors:

Application form……..#500.00

New licence……..#2,000.00

Renewal fees……#1,200.00 per annum

Pharmaceutical Chemists:

Processing fees……..#2,500.00 per annum

SECOND SCHEDULE

[Sections 9 and 20.]
[No. 4 of 2006.]

Form A

Patent and Proprietary Medicines Vendors Licence

Licence is hereby granted to ……. ……. of ……to sell patent and proprietary medicines within Nigeria subject to the provisions of the Pharmacy Law and Patent and Proprietary Medicines (Control) Law.

This licence expires on the 31st day of December, 20 ……..

Dated this ……..day of ……., 20 ……

…….

Licensing Authority

Fee for licence ……..

Form B

Sealing off of Premises

TO ALL THAT IT MAY CONCERN

Take notice that these premises ……
……have been sealed off by the order of the Pharmaceutical Inspector pursuant to section 18 (1) of the Patent and Proprietary Medicines (Control) Law.

Further take notice that whoever opens the above premises without authority or in the absence of a Pharmaceutical Inspector duly authorised, commits an offence and shall be prosecuted in accordance with section 18 (3) of the said Law.

Dated at ……this ……day of ……., 20 …….
(To be pasted on the main door or gate of the premises).

……..
Pharmaceutical Inspector

Form C

Notice of Seizure

To ……
……
……

Take notice that the drugs listed hereinafter and their description have been seized on the…….. day of ……., 20 ……..pursuant to section 19 of the

Patent and Proprietary Medicine (Control) Law during an Inspection visit to your premises at

……

……..

LIST OF DRUGS

No. Description

Quantity

……

……

……

……

……

……..

Dated this ……day of ……., 20 ……..

……

Signature of Inspector

I,

……

……

……

Signature

Form C—continued

* Servant to owner/agent to owner/owner of the said drugs confirm that the above drugs were seized from me as aforementioned.

* Delete as applicable.

Form D

COMPLAINT

AGAINST

……..

(Name of the person against whom complaint is made)

To: The Police Officer in charge

……

……

The Pharmaceutical Inspector based at ……..

……is formally making a complaint against the following

Name

……

……

Premises……

…….....

Situated at

……

…..

as follows: (State the nature of the complaint)

(*a*)

……

……..

(*b*)

……

……..

(*c*)

……

……

(*d*)

……

……

This is pursuant to the provisions of the Patent and Proprietary Medicines (Control) Law.

Dated at ……this …….day of ……., 20 ……

……..

Pharmaceutical Inspector

Form E

Order Of Disposal Of Impounded Drug

(To be filled in two copies, one copy to be kept by the Court and the other by a Hospital)

The Medical Superintendent,

……Hospital

……..

…… Court Case No. ……

Form E—continued

The underlisted drugs which were impounded by the Pharmaceutical Inspector from the premises at ……..and upon judgement entered against the owner are hereby released to you pursuant to the provisions of the Patent and Proprietary Medicines (Control) Law.

LIST OF DRUGS

No. Description

Quantity

……

……

……

……

Dated at ……this ……day of ……, 20 ……..

……..

Court Registrar

Delivered in the presence of:

……..

……..

Pharmaceutical Inspector

CERTIFICATION

I,

……..the Medical Superintendent of …… Hospital ……..hereby certify that the above listed drugs have been released physically to me on behalf of the Hospital pursuant to the provisions of the Patent and Proprietary Medicines (Control) Law.

Dated ……day of ……, 20 ……

Medical Superintendent

.....Hospital

THIRD SCHEDULE

List of Psychoactive

[Section 20.]

Hypnotics/Sedative/Tranquillisers

Diazepam.

Flurazepam hydrochloride.

Chlordiazepoxide.

Bromazepam.

Medazepam.

Promethazine hydrochloride.

Promazine hydrochloride.

Nitrazepam.

Chlorpromazine hydrochloride.

Trizolobenzodiazepine.

Medazepam.

Temazepam.

Oxazepam.

Clorazepate.

Anticonvulsants

Sodiumvelproate.

Primidone.

Biperiden.

Diperiden.

D-Dopa.

Chlorretiazole.

Clonazepan.

Clonazepam.

Benztropine mesylate.

Metizene hydrochloride.

Anti-emetics

Meclozine hydrochloride.

Lorazepam.

Flupenthical decancate.

Glutethimide.

Thiopentone.

Niaprazin.

Flumitrazepam.

Trifluoperazine.

Promedrazine theoclabe.

Butobarbitone.

Meprobamate.

Haloperidol.

Thioridazine hydrochloride.

Primozide.

Ketazolan.

Trifluoperidol.

Muscle Relaxants

Suxamethonium.

Gallamine.

Pancuroniam bromide.

Styramate armour.

Mephenesin.

Orphenadrine.

Methocarbamol.

Central Nervous System Stimulants

Pyritinol dihydrachloride.

Prochlorperazine.

Nikethamide.

Thiethylperazine dimaleate.

Antihistamines

Chlorpheniramine maleate.

Brompheniramine.

Piprinhydrinate.

Metoclopromide.

Phenindamine tartrate.

Piracetam.

Clomipramine.

Merital (R).

Fluphenazine hydrochloride.

Imipramine.

Trimipramine.

Hepyramine maleate.

Diphenylpyraline hydrochloride.

Buclizine hydrochloride.

Carbinoxamine maleate.

Phenylephadrine hydrochloride.

Fenezolone.

Amitryptiline.

Fluphenazine decanoabe.

Bibenzepin hydrochloride.

Thioridazine hydrochloride.

Amitriptyline hydrochloride.

Miscellaneous

Naestigmine methyl sulphate bromide.

CHAPTER P1

PATENT AND PROPRIETARY MEDICINES (CONTROL) LAW

SUBSIDIARY LEGISLATION

No Subsidiary Legislation
