

GUIDELINES ON THE ISSUANCE OF PATENT AND PROPRIETARY MEDICINES VENDOR'S LICENSE

1. INTRODUCTION

The Licensing of non-pharmacists to stock, market and sell simple medicinal remedies is entrenched in the 1958 Poisons and Pharmacy Act, Cap 152, Poisons and Pharmacy Act 535 Abuja Laws and Pharmacists Council of Nigeria Act 91 of 1992. This was an attempt to redress the lopsided distribution of the very few healthcare facilities, public and private health sector alike, available at that time.

Also, an important element of the National Drug Policy is the adequate provision, accessibility and availability of essential drugs, which are effective, affordable, safe and of good quality in all aspects of the National Health System.

2. SCOPE

These guidelines are designed to address the issuance of Patent and Proprietary Medicines Vendor's Licence (PPMVL) in the country under the following headings:

- (i) Licensing authority
- (ii) Eligibility
- (iii) Mode of application
- (iv) Fees for application
- (v) Issuance and renewal of licence
- (vi) Validity of licence
- (vii) Orientation and continuing education for holders of patent and proprietary medicines vendor's licence
- (viii) Monitoring and inspection

3. LICENSING AUTHORITY

The Licensing Authority is the Pharmacists Council of Nigeria (PCN) established under Decree 91 of 1992.

4. **ELIGIBILITY**

An applicant for the patent and proprietary medicines vendor's licence shall produce evidence to the satisfaction of the licensing authority:

(a) in the case of an individual

- i. that he has attained the age of twenty-one (21) years;
- ii. that he is of good character and certified as such by two satisfactory referees
- iii. that such individual shall be able to read and write in English Language and

(b) in the case of a person other than an individual, that the nature of the business is such as to warrant the sale of medicines.

5. **MODE OF APPLICATION**

- i. Application shall be made in the applicant's own handwriting indicating the exact location, address where the intended business is to be undertaken. Post Office Box (P. O. Box) or Private Mail Bag (P.M.B) shall not be accepted.
- ii. The application shall be addressed to the Registrar, Pharmacists Council of Nigeria through the Director of Pharmaceutical Services of the State, where the applicant wants to operate.
- iii. Letters of recommendations from two (2) people as referred to in S.4 (a)(ii) shall accompany the application. Three passport photographs, all of which will be endorsed by one referee, shall be attached to the application.
- iv. The applicant shall forward a current income tax clearance certificate.
- v. Each application shall be accompanied with a non-refundable application fee.

6. **PROCEDURE FOR THE ISSUANCE OF LICENCE**

The following procedure shall be adopted for the issuance of Patent and Proprietary Medicines Vendor's Licence (PPMVL):

- (a) Submission of duly completed application form;
- (b) Interview of applicant by the PPMV Licensing Committee in the State;
- (c) Payment of a prescribed inspection fee;

- (d) Inspection of premises shall be carried out by Pharmaceutical inspectors;
- (e) A satisfactory report to the PCN by the State PPMVL Committee;
- (f) Issuance of licence by PCN on payment of prescribed registration fee;
- (g) Applicants shall be issued a booklet containing the list of medicines approved for sale by the licensing authority;
- (h) Attendance at PPMV orientation course.

Note

Licence holders shall display the licence in the shop conspicuously and their business name on a signpost in front of their premises. The business name shall also carry the wordings "Patent Medicines Shop" conspicuously written. Such names as "Drug Stores" or "Medicine Stores" are prohibited.

7. **FEES FOR LICENCE**

The licence fee shall be as specified in Schedule 1 to these guidelines and the Pharmacists Council of Nigeria may review such fees from time to time.

8. **CONDITIONS FOR RENEWAL OF LICENCE**

The following conditions shall guide the renewal of licence:

- (a) All applications must be submitted on or before the 31st of January of each year;
- (b) All licences are to be renewed annually subject to satisfactory inspection report;
- (c) All licenced premises for the sale of Patent and Proprietary Medicines shall be subject to periodic inspection by Pharmaceutical Inspectors appointed by the Pharmacists Council of Nigeria.
- (d) Evidence of attendance at Continuing Education Programme at least once in every two years;
- (e) Payment of prescribed fees;
- (f) Satisfactory performance by the licensee.

9. **VALIDITY OF LICENCE**

The licence shall expire on the 31st of December of the year of issuance. However, the licensing authority reserves the right to revoke a licence during its validity period if there is any breach, false declaration or documentation.

10. **ORIENTATION AND CONTINUING EDUCATION**

Every new licenced holder shall be required to attend an orientation course. Thereafter, the licence holder shall be required to attend a Continuing Education Programme, at least, once in every two (2) years. Such courses shall be organized at state level by the Pharmacists Council of Nigeria in collaboration with the state PPMVL Committee.

11. **MONITORING AND INSPECTION**

Licensed premises shall be subject to periodic monitoring and inspection by Pharmaceutical Inspector(s);

12. **ROLES AND RESPONSIBILITIES**

- (i) The Federal Ministry of Health
 - (a) Shall formulate relevant policies;
 - (b) Shall give directives of a general character to the Pharmacists Council of Nigeria relating to the implementation of these guidelines and it shall be the duty of the Pharmacists Council of Nigeria to comply and give effect to the directives;
- (ii) Pharmacists Council of Nigeria (PCN)

The roles of the Pharmacists Council of Nigeria (PCN) shall include but not limited to the following:

- (a) Shall provide and issue the PPMVL;
- (b) Shall provide the receipts for the various fees;
- (c) Shall disburse funds to states according to the sharing formula as contained in Schedule II of these guidelines;
- (e) Shall accredit pharmaceutical inspectors;
- (f) Shall approve State PPMVL Committees;

- (g) Shall enforce sanctions and compliance;
- (h) Shall provide approved Patent Medicines list.

(iii) State Ministries of Health

- (a) Shall facilitate the activities of State PPMVL Committees;
 - (b) The Director of Pharmaceutical Services (DPS) shall arrange for pre-approval and routine inspection of new and licenced premises respectively;
 - (c) The DPS shall collect revenue in respect of PPMVL and pay same to PCN.
- (iv) Patent and Proprietary Medicine Vendors and Licence (PPMVL) Committee
- (a) Shall monitor activities of vendors and make quarterly and annual returns to Pharmacists Council of Nigeria (PCN);
 - (b) Recommend Pharmaceutical Inspectors for accreditation by the Pharmacists Council of Nigeria;
 - (c) Shall conduct interview for applicants;
 - (d) Shall recommend successful applicants to PCN for licence;
 - (e) Shall organise Orientation Course and Continuing Education Programme for vendors in collaboration with PCN.

13. COMPOSITION OF STATE PPMVL COMMITTEE

The Committee shall be composed of:

- (a) Director of Pharmaceutical Services (DPS) of the State (Chairman);
- (b) Director Pharmaceutical Services, State Hospitals Management Board (Member);
- (c) Chairman of State Pharmaceutical Society of Nigeria (PSN) or his representative (Member);
- (d) One representative of NAFDAC (Member);
- (e) A member of the Civil Society nominated by PCN;
- (f) Head of Pharmaceutical Inspectorate Unit in the State Directorate of Pharmaceutical Services (Member/Secretary).

SCHEDULE I

1. No Patent and Proprietary Medicines Vendor Licence Holder shall operate unless the under-listed fees have been paid accordingly. The fees so listed shall be reviewed from time to time. All payment must be in bank draft payable to Pharmacists Council of Nigeria.

(a)	Application fee	-	N500.00
(b)	Pre-approval inspection fee	-	N1,000.00
(c)	Registration Licence	-	N2,000.00
(d)	Renewal Inspection Fee	-	N1,000.00
(e)	Registration Renewal	-	N1,000.00

SCHEDULE II

The Pharmacists Council of Nigeria shall collect all revenue and disburse as follows:

(a)	Application fees	-	100% to PCN
(b)	Inspection fees	-	100% to State PPMVL Committee
(c)	Licensing fees	-	50% to States and 50% to PCN

14. MISCELLANEOUS PROVISIONS

- a. All Patent or Proprietary Medicines shall be sold in the original container properly secured.
- b. No holder of a PPMVL shall repack a patent and proprietary medicine.
- c. Any person who does any act likely to prevent or obstruct the carrying into effect of the provisions of these guidelines is guilty of an offence.
- d. A person aggrieved in pursuance to the enforcement of the provisions of these guidelines may appeal to the Pharmacists Council of Nigeria (PCN).
- e. The licensing authority shall not issue licence to an applicant where the circumstances, not limited to the following are shown to exist, that the applicant is:

- a. Bankrupt or insolvent
- b. An ex-convict
- c. In disobedience of Council's directives
- d. Involved in practices outside the scope of the licence.
- f. The PCN shall exercise powers generally and do such things that are incidental to carrying into effect the provisions contained in these guidelines.
- g. Any person operating a Patent Medicines business without a licence or who contravenes any other provisions of these regulations shall be guilty of an offence, and is liable on conviction to a fine not exceeding N500,000.00 or to a term of imprisonment not exceeding two (2) years or to both such fine and imprisonment.
- h. The PCN or its representative shall have power to seal erring premises.
- i. Where it is satisfied that a licence holder is in breach or in default of his responsibility under the prevailing guidelines or law in force, the licensing authority may, if it deems fit, revoke, withdraw any licence issued and/or strike off his name and premises from the register, but without prejudice to administrative charges that may be imposed on the defaulter.
- j. Notwithstanding anything to the contrary in any enactment or law the Federal High Court, State High Court, and Magistrate Court shall have jurisdiction to try offences under these guidelines.
- k. The following shall have exclusive powers to prosecute offender(s) under these guidelines
 - i. Attorney General of the Federation
 - ii. Pharmacists Council of Nigeria
 - iii. The Nigeria Police