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PHARMACISTS COUNCIL OF NIGERIA

REVIEWED PPMVL GUIDELINES FOR THE ISSUANCE OF PATENT AND PROPRIETARY MEDICINES VENDOR'S LICENCE

[23*rd Day of August*, 2019] Commencement.

In exercise of the powers conferred by sections 1, 13, 14, 21 and 24 of the Pharmacists Council of Nigeria Act (Cap P17 Laws of the Federation of Nigeria (LFN) 2004 and all powers enabling it in that behalf, the Council of the Pharmacists Council of Nigeria with the approval of the Honourable Minister of Health, hereby makes the following Regulations :

Introduction

1. The licensing authorization of non-Pharmacists for stocking, marketing and selling of simple medicinal remedies is entrenched in the 1958 Poisons and Pharmacy Act Cap. S35 (LFN 2004). This was an attempt to redress the lopsided distribution of the very few healthcare facilities in public and private sectors alike, available at that time. It is instructive to note that the issuance of Patent and Proprietary Medicines Vendors Licence is tailored towards areas where pharmaceutical services are not readily available such as rural areas and hard to reach remote areas. The need remains a relevant aspect of Nigeria's healthcare delivery system today.

An important element of the National Drugs Policy is the adequate provision, accessibility and availability of essential drugs, which would be effective, affordable, safe and of good quality in all aspects of the National Health System. The Pharmacists Council of Nigeria (PCN) takes this challenge very seriously and has mobilized all resources at its disposal to effectively address it. The Guidelines demonstrates the commitment of the PCN towards facilitating the delivery of simple medical remedies at the grass root level in every nook and cranny of Nigeria.

Scope.

2. The Guidelines are designed to address the issuance of the Patent and Proprietary Medicines Vendors Licence (PPMVL) in Nigeria, under the following sub-themes :

(*i*) the licensing authority ;

(*ii*) eligibility ;

(*iii*) requirements for and application ;

(*iv*) application fee required ;

(*v*) issuance and renewal of the licence ;

(*vi*) validity of the licence ;

(*vii*) mandatory orientation and continuing education for holders of the patent and proprietary medicines vendors licence ; and

(*viii*) monitoring and inspection.

The Licensing Authority.

3. By virtue of the Poison and Pharmacy Act, Cap 535 and the prescriptions of the Honourable Minister of Health vide the letter Reference No. FHC/L/CS/97/74 and dated 14th April, 2003, the Pharmacists Council of Nigeria (PCN) is the Licensing Authority for the issuance and renewal of Patent and Proprietary Medicines Vendor's Licence throughout Nigeria.

Eligibility.

4. An applicant for the Patent and Proprietary Medicine Vendors Licence (PPMVL) shall produce evidence to the satisfaction of the Licensing Authority that the applicant :

(*i*) has attained the age of twenty-one (21) years ;

(*ii*) is of good character and certified as such by two satisfactory referees ;

(*iii*) is able to read and write in english language ; and

(*iv*) shall have obtained at least a Secondary School leaving certificate or Pharmacy Technician Certificate from a Pharmacists Council of Nigeria (PCN) Accredited Institution.

Requirements for an Application.

5.—(*i*) An Applicant shall be made in the applicant's own handwriting, indicating the exact location and address where the intended business is to be undertaken. A Post Office Box (P.O. Box) or a Private mail Bag (P.M.B.) shall not be accepted as a valid address.

(*ii*) The application shall be addressed to the Registrar, Pharmacists Council of Nigeria (PCN) and submitted at the PCN State Office, where the applicant intends to operate the business.

(*iii*) The applicant shall attach copies of the Pharmacy Technician Certificate obtained from a PCN Accredited Institution and current Annual Permit.

(*iv*) Letters of recommendations from two (2) reputable referees : one of whom shall a registered and currently licenced Pharmacist.

(*v*) Three passport photographs, all of which shall be endorsed by one of the applicant's referee, shall be attached to the application.

(*vi*) The applicant shall produce a current income tax clearance certificate.

(*vii*) Each application shall be accompanied with a non-refundable application fee as specified by the PCN.

Procedures for the Issuance of the Licence.

6. The following procedure shall be adopted for the issuance of the Patent and Proprietary medicine Vendors Licence (PPMVL) :

(*i*) Submission of a duly completed application form :

(*ii*) Interview of the applicant by the State PPMVL Committee :

(*iii*) Payment of the prescribed inspection fee ;

(*iv*) Inspection of the proposed shop by the State PPMVL Committee :

(*v*) A satisfactory report of the PCN by the State PPMVL Committee :

(*vi*) Issuance of the licence by the PCN on payment of the prescribe registration fee ; and

(*vii*) The applicant shall be issued a booklet containing the list of medicines approved for sale by the licensing authority (the PCN) ; and

(*viii*) The applicant's mandatory attendance of a Patent and Proprietary Medicine vendor's (PPMV) orientation course.

Note :

A PPMVL holder shall conspicuously display the licence in their shop, as well as their business name on a signpost in front of their premises. The business name shall also carry the wordings : "Patent Medicine Shop". The use of the names, "Drug Store" or "Medicine Store", etc. is prohibited.

Licence Fee.

7. The licencing fee shall be as specified in Schedule I to these Guidelines and reserves the right to review the fee from time to time.

Conditions for the Renewal of the Licence.

8. The following conditions shall guide the renewal of the PPMV licence :

(*a*) All applications for the renewal of the licence must be submitted on or before the 31st January of the year ;

(*b*) The licence must be renewed annually, subject to a satisfactory inspection report :

(*c*) All licenced shops for the sale of patent and proprietary medicine shall be subject to the periodic inspection by Pharmaceutical inspectors appointed by the Pharmacist Council of Nigeria ;

(*d*) Evidence of attendance of a Continuing Education Programme (CEP) at least once in every two years ;

(*e*) Payment of the prescribed fees ; and

(*f*) Satisfactory performance of the licencee.

Validity of the Licence.

9. 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 of the conditions for granting it or proof of false declaration or documentation.

Orientation and Continuing Education.

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

Monitoring and Inspection.

11. Licenced shops shall be subject to periodic monitoring and inspection by accredited Pharmaceutical inspectors who shall submit their reports to the Pharmacists Council of Nigeria.

Roles and Responsibilities of the Regulatory Authorities.

12.—(*i*) The Federal Ministry of Health

It shall give directives of a general character to the Pharmacists Council of Nigeria relating to the implementation of these Guidelines.

(*ii*) The Pharmacists Council of Nigeria (PCN)

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

(*a*) shall formulate relevant policies for the issuance of the licence;

(*b*) issuance and renewal of the PPMVL;

(*c*) provision of valid receipts for all fees collected;

(*d*) provision of the application forms for the PPMVL;

(*e*) disbursement of funds to states according to the sharing formula specified in Schedule II of the Guidelines;

(*f*) accrediting pharmaceutical inspectors;

(*g*) approval of the compensation of the State PPMVL Committee;

(*h*) enforcing appropriate sanctions and due compliance with the provisions of these Guidelines; and

(*i*) producing and updating an approved Patent Medicines Certificate.

(*iii*) The State Ministries of Health

The State Ministries of Health are charged with the following responsibilities:

(*a*) facilitate the activities of State PPMVL Committees;

(*b*) ensure that the Director of Pharmaceutical Services (DPS) makes adequate arrangements for the pre-approval and routine inspection of new licensed premises respectively.

(*iv*) The Patent and Proprietary Medicine Vendor's Licence (PPMVL) Committee shall:

(*a*) monitor the activities of patent and proprietary medicines vendors and submit quarterly and annual reports on them to the Pharmacists Council of Nigeria (PCN);

(*b*) recommend Pharmaceutical Inspectors for accreditation by the Pharmacists Council of Nigeria;

(*c*) conduct interviews for applicants for the PPMVL;

(*d*) recommend successful applicants to the PCN for the PPMV licence;

(*e*) organise effective Orientation and Continuing Education Programmes for patent and proprietary medicines vendors, in collaboration with the PCN.

13. Membership of the committee shall consist of : Composition of the State PPMVL Committee.

(*i*) the Director of Pharmaceutical Services of the State (*Chairman)* ;

(*ii*) the Director of Pharmaceutical Services, State Hospital management Board (*Member*) ;

(*iii*) the Head of the Pharmaceutical Inspectorate Unit in the State's Directorate of Pharmaceutical Services (*Member*) ;

(*iv*) the Chairman of the State Chapter of the Pharmaceutical Society of Nigeria (PSN) or his representative (*Member*) ;

(r) the Chairman of the State Chapter of the Association or Community Pharmacists of Nigeria ACPN) or his representatives (*Member*) ;

(*vi*) one representative of NAFDAC (*Member*) ;

(*vii*) a member of the Civil Society nominated by the PCN (*Member*) ;

(*viii*) a representative of the PPMV holders nominated by the PCN ; and

(*ix*) the PCN Zonal/State Officer and/or his representative (*Member and Secretary*).

14.—(*a*) All patent or proprietary medicine shall be sold in their original containers, properly secured. Miscellaneous Provisions.

(*b*) No holder of the PPMVL shall re-pack patent or proprietary medicines.

(*c*) Any person who does anything likely to prevent or obstruct the effective implementation of the provisions of these Guidelines shall be guilty of an offence.

(*d*) Any aggrieved person, pursuant to the enforcement of the provisions of these Guidelines, may appeal to the Pharmaceutical Council of Nigeria.

(*e*) The licensing authority shall not issue a licence to an applicant where any, but limited to the circumstances are shown to exist that the applicant is :

(*i*) Bankrupt or insolvent,

(*ii*) An ex-convict,

(*iii*) In disobedience of the Council's directives, or

(*iv*) Involved in practices inimical to the issuance of the licence.

(*f*) The PCN shall exercise its powers generally and take such measures as are incidental to the effective implementation of the provisions of these Guidelines.

(*g*) Any patent and proprietary medicines vendor without a licence, or who contravenes any of the provisions of these Guidelines shall be guilty of an offence, and shall be liable, on conviction, to a fine not exceeding N500,000.00, or to a term of imprisonment not exceeding two years or to both.

(*h*) The PCN or its representatives shall have powers to seal the shops of PPMVL Holders or any person(s) who contravenes any of the provisions of these Guidelines and where the seal is tampered with, the vendor shall pay the administrative fee charges.

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(*h*) The PCN or its representatives shall have powers to seal the shops of PPMVL Holders or any person(s) who contravenes any of the provisions of these Guidelines and where the seal is tampered with, the vendor shall pay the administrative fee charges.

(*i*) Where the licensing authority is satisfied that a licence holder is in breach or in default of the responsibilities under these Guidelines, or laws in force, the licensing authority may, if it deems fit, revoke any licence issued or strike off the name and shops from the register, but without prejudice to administrative charges that may be imposed on the defaulter.

(*j*) The PCN is the first port of call for intending PPMVL Holders.

(*k*) Notwithstanding anything to the contrary in any enactment or law, the Federal High Court, the State High Court, and the Magistrate Court shall have jurisdiction to try offences under these Guidelines.

(*l*) The Following shall have exclusive powers to prosecute offenders under these Guidelines :

(*i*) the Attorney-General of the Federation,

(*ii*) the Pharmacists Council of Nigeria, and

(*iii*) the Nigeria Police.

SCHEDULE I

The Patent and Proprietary Medicines Vendors Licence Holder shall operate unless the under listed fees have been paid to the Pharmaceutical Council of Nigeria (PCN).

(*a*)	Application Fee	₦500.00
(*b*)	Pre-approval Inspection Fee	₦5,000.00
(*c*)	Registration Licence	₦5,000.00
(*d*)	Renewal of Licence Inspection Fee ..	₦5,000.00
(*e*)	Registration Licence Renewal	₦5,000.00
(*f*)	Administrative Charges	N20,000.00

SCHEDULE II

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

(*a*)	Application Fees ..	100 % to the PCN
(*b*)	Inspection Fees ..	100% to the State PPMVL Committees
(*c*)	Licencing Fees ..	50% to the State and 50% to the PCN

MADE at Abuja this 23rd day of August, 2019.

DR. E. OSAGIE EHANIRE, MD, FWACS.
The Honourable Minister
Federal Ministry of Health