

Extraordinary



Federal Republic of Nigeria Official Gazette

No. 81

Lagos - 12th August, 2005

Vol. 92

Government Notice No. 154

The following is published as Supplement to this Gazette:

<i>S. I. No.</i>	<i>Short Title</i>	<i>Page</i>
13	Pharmacists Council of Nigeria Act (1992 No. 91). <i>Registration of Pharmaceutical Premises Regulations, 2005</i>	153-157

.Printed and Published by The Federal Government Press, Lagos, Nigeria
FGP 236/1112005/650 (OL 70)

Annual Subscription from 1st January, 2005 is Local : ₦1,500.00 Overseas : ₦21,500.00 [Surface Mail]
₦24,500.00 [Second Class Air Mail]. Present issue ₦350.00 per copy. Subscribers who wish to obtain
Gazette after 1st January should apply to the Federal Government Printer, Lagos for amended Subscriptions.

**PHARMACISTS COUNCIL OF NIGERIA ACT
(1992 No. 91)
REGISTRATION OF PHARMACEUTICAL
PREMISES REGULATIONS, 2005.**

Commencement: 26th July, 2005

In exercise of the powers conferred upon the Pharmacists Council of Nigeria (hereinafter referred as the Council) by sections 1 and 24 of the Pharmacists Council of Nigeria Act and all other powers enabling the Council in that behalf, the Council with the approval of the Minister of Health hereby made the following Regulations:

1. All applicants for registration of new pharmaceutical premises or renewal of old premises shall complete the application form which shall be accompanied with the following documents :
 - (a) application letter to register the premises;
 - (b) annual licence to practice pharmacy;
 - (c) prescribed fees in Bank Draft payable to the Council ;
 - (d) letter of resignation from previous employment(if applicable);
 - (e) letter of acceptance of resignation (if applicable) ;
 - (f) letter of appointment' as the Superintendent Pharmacist in the new premises;
 - (g) legal agreement between the Superintendent Pharmacist and his employer;
 - (h) Company's Certificate of Incorporation (Evidence of registration of business name is acceptable) ;
 - (I) Article and Memorandum of Association;
 - (j) Form C. 07 showing names and particulars of Directors ;
 - (k) NYSC Discharge or Exemption Certificate;
 - (l) letter of undertaking by the Superintendent Pharmacist to the effect that he has only one full time job; and
 - (m) letter of undertaking by the Managing Director of the Company to the effect that all pharmaceutical business shall be under the direct, personal control and management of the Superintendent Pharmacist.

- 2.-(1) Where the pharmaceutical premises sought to be registered is for manufacturing, in addition to the documents listed in subsection (1) of this section, the application shall be accompanied with the following:
 - (a) list of products to be manufactured;
 - (b) list of equipment for Production and Quality Control Departments ;
 - (c) list and sources of suppliers of raw and packaging materials;
 - (d) standard Operating Procedures (SOP);
 - (e) factory layout;

Application for registration or renewal of manufacturing and retail pharmacy

- (f) production Flow Chart ;
- (g) water source and treatment facilities;
- (h) water analysis report (Raw and treated water) ;
- (I) list of qualified staff showing qualifications and duty ;
- (j) organogram ;
- (k) disposal of poison records;
- (l) prescribed inspection fees in Bank Draft payable to the PHARMACISTS COUNCIL OF NIGERIA; .
- (m) product licenses for all products (Routine inspection) ; and
- (n) list of all distributors and distributions records (Routine inspection).

- Retail Pharmacy. (2) Where the premises sought to be registered is a Retail Pharmacy, the company shall be wholly owned by a registered pharmacist or in partnership with other registered pharmacists.
- Wholesale/ Distribution and importation. 3.- {1) For a pharmaceutical premises involved in whole: ale, distribution and importation of drugs, poison and devices, there shall be at least one registered pharmacist on the Board of Directors of the Company.
- (2) The business shall be carried out under the direct personal control and management of a Superintendent Pharmacist.
- Manufacturing 4.- (1) Where the primary object of the company is pharmaceutical manufacturing, then, the provisions of Regulation 3 shall apply.
- (2) Each production line shall be supervised by a production pharmacist.
- (3) The over-all quality assurance of the establishment shall be the responsibility of the Superintendent Pharmacist.
- (4) The Production and Quality Control Managers shall report to the Superintendent Pharmacist.
- Proper record keeping 5. { 1) Manufacturers, Importers, Wholesalers and Retailers of drugs, Poisons and devices shall keep appropriate records of the receipt and disposal of drugs.
- (2) Any unauthorized disposal of drugs shall be penalized in accordance with these regulations.
- (3) Retail outlets of drugs, poisons and devices shall keep proper records of the following:
- (a) all receipts of purchases made;
 - (b) disposal of Poisons ;
 - (c) ledgers/bin cards; and
 - (d) dispensed prescription.

- (4) Wholesalers/Distributors of drugs, poisons and devices shall keep records as provided in subsection (3) of the section.
- (5) Importers of drugs, poisons and devices shall keep proper records of the following:
- (a) all relevant import documents; and
 - (b) documents provided for under sub-section 3 of this section.
- (6) Manufacturers of drugs, poisons and devices shall at all times keep proper records of all documents/information relating to :
- (a) the purchases of raw materials;
 - (b) production and quality control activities; and
 - (c) distribution and sales of finished products.
6. Only registered pharmacists shall market ethical products. Marketing of.
.Pharmaceutical
product.
- 7.- { 1) Every Hospital shall cause its Pharmacies to be registered with the Hospital Pharmacy. Pharmacists Council of Nigeria in accordance with the guidelines regulating the operations of hospital pharmacy prescribed by Council. Hospital
Pharmacy.
- (2) The Council shall ensure that inspection is undertaken from time to time of all hospital pharmacies in its attempt to maintain standards.
- (3) The fees payable for registration of hospital pharmacies shall be as prescribed by Council.
- (4) All existing hospital pharmacies in Nigeria not registered with the Council before the coming into force of these regulations shall be inspected and registered with effect from 1st January, 2005.
- (5) All hospitals shall employ and maintain a minimum number of registered pharmacists as prescribed by Council to handle the pharmaceutical needs of the hospital.
- 8.- { 1) Names registered by the Pharmacists Council of Nigeria only shall be used on the sign post of a pharmacy. General
provisions.
- (2) Registered pharmacist-owned premises only shall display the Pharmaceutical Society of Nigeria (PSN) Pharmacy Emblem.
- (3) In the absence of the Superintendent Pharmacist, there shall be a resident/locum pharmacist to take charge of the pharmacy. .
- (4) It shall be an offence for any registered pharmacist to hold more than one full time job. .
- (5) Any request for temporary closure of premises shall not be for more than 2 years and the renewal fee must be paid for the period of closure.

(6) The fees payable in respect of the registration of any set of premises is as prescribed by Council from time to time.

(7) The Registrar shall send to a person who has not paid a retention fee which is payable by him, a demand for payment thereof which demand shall be by registered letter addressed to the person at his registered premises and or to his last known place of abode if the place is different from his registered premises.

(8) The registrar shall, notify the Council of the failure to pay on the part of a person on whom a demand has been made.

(9) The Council shall provide sufficient forms (for registration of premises and retention of name in the register) to the various State Director of Pharmaceutical Services (DPS) including Abuja by the 30th day of September of every year.

Penalties for late payment of practicing fees and fees for registration of pharmaceutical premises.

9.- (1) Any registered pharmacist who fails to pay the prescribed practicing fee by the 31ST day of January of every year shall in addition to paying the fee provided, pay a fine equivalent of 50% (fifty per cent) of the applicable fee.

(2) Any pharmaceutical premises that remains unregistered by 31st day of January of every year shall in addition to paying the fee prescribed, pay a fine equivalent of 50% (fifty per cent) of the applicable fee.

(3) Pharmaceutical premises that remain unregistered by the 31st day of of each year, shall be closed.

(4) Any pharmacist found guilty 'of a criminal offence by a Court of competent jurisdiction or Tribunal shall not be registered until the Pharmacist Council of Nigeria Tribunal decides otherwise.

Pre-regis-
tration
Inspection.

10. Inspection of any sector of the Pharmaceutical Industry for registration shall attract a fee of ₦10,000.00 (ten thousand naira) for the first two visits and subsequent visit shall attract the sum of ₦20,000.00 (twenty thousand naira) per visit.

Situation in which the PSN emblem may be forfeited:

11.- (1) Any Pharmaceutical Society of Nigeria (PSN) Emblem found in an unauthorized location shall be confiscated.

(2) Display of any fake or imitation of Pharmaceutical Society of Nigeria (PSN) Emblem shall attract a fine of N10,000.00 (ten thousand naira) in addition to forfeiture of the Emblem.

(3) Any registered pharmacist who forwards more than one application for registration of premises for more than one premises shall :

(a) be deemed to have committed an offence and shall be recommended to appear before the Investigating Panel;

(b) have his premises closed down; and

(c) be referred to the Disciplinary organs of Council for appropriate action.

Offences and Penalty.

12. A person who contravenes or fails to comply with the provisions of these regulations shall be guilty of an offence and liable on conviction to a fine of N20,000.00 (twenty thousand naira).

13. In these regulations, unless the context otherwise requires:

Interpretation.

"Pharmaceutical Society of Nigeria Emblem" means the symbol as patented by the Registrar of Patents.

14. These regulations may be cited as the Registration of Pharmaceutical Premises Regulations 2005.

Citation.

(PROF) FESTUS A. OGUNBONA
Chairman, Pharmacists Council of Nigeria.