

Extraordinary



Federal Republic of Nigeria Official Gazette

No. 79

Lagos - 10th August, 2005

Vol. 92

Government Notice No. 152

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) Inspection, Location and Structure of Pharmaceutical Premises Regulation 2005	147-151

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

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

S.I 13 of 2005

**PHARMACISTS COUNCIL OF NIGERIA ACT
(1992 No. 91)
INSPECTION, LOCATION AND STRUCTURE 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.- (1) There is hereby established a Pharmaceutical Inspectorate Division.

Establishment of
Pharmaceutical
Inspectorate
Division.

(2) The Pharmaceutical Inspectorate Division shall consist of registered pharmacists designated as pharmaceutical inspectors who shall be appointed by the Council.

2.-(1) Pharmaceutical Inspectors appointed by the Council shall have the power in the Course of carrying out their duties, at reasonable time and on production of their identity cards if so required to :

Powers of
Pharmaceutical
Inspectors.

(a) enter any premises in which they reasonably believe that an article to which this regulation applies is manufactured, prepared, preserved, packaged or sold therein;

(b) examine any article in the premises to which this regulation applies which they reasonably believe is used as is capable of being used for the manufacture, preparation, preservation, packaging, storage or sale of any such article;

(c) take sample or specimen of any article to which these regulations apply;

(d) open and examine within on the premises any container or package which they reasonably believe may have any articles to which these regulation apply and would help in their investigations;

(e) examine any books, documents or other records found on the premises which they reasonably believe may contain information relevant to the enforcement of these regulations and make copies thereof; and

(f) seize and detain for such time as may be necessary, any article by means of which he reasonably believes any provision of these regulations have been contravened.

(2) Pharmaceutical Inspectors shall have the power to seize any drugs, poisons, devices or wares in any unauthorized premises if they have reasonable cause to suspect that such items are unwholesome. impure, fake, adulterated or banned.

Duty of owners
of
Pharmaceutical
Premises.

3.-{ I) The owner or person in charge of a pharmaceutical premises and every person found thereon shall give all reasonable assistance to Pharmaceutical Inspectors, including, making available to the Inspectors all such information as they may require for the purpose of carrying out these regulations.

(2) Every person who conducts in any premises business which include the retail sales of drugs and poisons shall state on being required by an inspector, the owner of the business and produce all books kept in accordance with the provisions of these regulations.

Seizure of
articles

4.-{1) Any article seized under these regulations shall be kept or stored in such a place as the inspectors may direct.

(2) Any article seized by an inspector pursuant to these regulations may, be submitted to an analyst for examination.

(3) The analyst on making such examination shall, issue a report setting out the result of such examination.

(4) The Pharmaceutical Inspector shall on demand, deliver a copy of such report to the owner of the article if the article is subject of proceedings under these regulations.

(5) If the article upon examination is found to conform to the requirements of these regulations, the Pharmaceutical Inspector shall return the article to the owner or person from whom it is seized.

Special
powers of
the Council

5.-{1) The Council shall have the power to:

(a) cause investigations to be conducted to ascertain persons involved in offences under this Regulation;

(b) determine whether any person has committed an offence under this Regulations; and

(c) prosecute offenders in a competent Court of Law.

Citing of
Pharmaceutical
Premises

6.-{ I) Pharmaceutical premises shall not be located in :

(a) motor parks;

(b) environment where commercial activities and enterprises are standing and growing very close together, and

(c) market places including kiosks and road-side stalls.

(2) Any pharmaceutical premises surrounded or covered completely by a growing market or standing close to it shall be moved to another suitable location two years after formal notification to do so by Pharmacists Council of Nigeria.

(3) Pharmaceutical premises within a shopping centre shall not be more than three and they shall be well spaced out.

(4) Pharmaceutical premises shall be sited not less than two hundred metres from each other.

7.-{ I) A pharmaceutical premises shall :

(a) not be less than 30 square metres; and

(b) have a ceiling height of at least 3.05 metres.

(2) A pharmaceutical premises shall be made of concrete walls **and not in** the form of kiosk or bull-doff.

(3) The floor of a pharmaceutical premises shall be made of concrete, tiles or terrazzo.

(4) The shop in a pharmaceutical premises shall :

(a) be well painted;

(b) have shelves which are well arranged and painted; and

(c) have a proper ceiling of the roof.

(5) The shop in a pharmaceutical premises shall :

(a) have a well demarcated area for making prescriptions, counselling patients and dispensing drugs; and

(b) contain in the dispensing area, scheduled prescription drugs which shall be locked in the absence of the Superintendent Pharmacist.

8.- { I) There shall be provided in pharmaceutical premises, an office for the Superintendent Pharmacist.

(2) The name of the Superintendent Pharmacist shall be on display on a name hook at the entrance of the Pharmacy.

(3) The Superintendent Pharmacist shall be in a white overall with proper designation by way of name tag while on duty.

(4) A pharmaceutical premises shall be situated in a good sanitary environment.

9. There shall be provided in a pharmaceutical premises:

(a) ceiling fans or air-conditioners to ensure proper ventilation;

(b) metric balances, weight and measures in the compounding room (where applicable) ;

(c) a refrigerator for thermo labile preparations;

(d) adequate pallets and shelves for store and warehouse for pharmaceutical companies involved in distribution and or importation of drugs;

(e) good water supply from the public water supply system;

Structure of a
Pharmaceutical
Premises

Office of
Superintendent
Pharmacist

Facilities to be
provided in a
Pharmaceutical
Premises

(f) facilities for filtration to achieve the desired quality if water is required for the compounding of drugs ;

(g) proper records of the purchases and sales made therein ;

(h) disposal of poisons book which shall be properly kept; and

(I) copies of recent editions of reference books including:

(i) B.P.C. ;

(i/) Extra Pharmacopoeia;

(ii/) I.P. ;

(iv) B.N.F. ;

(v) National Formulary and Essential Drugs List;

(VI) Pharmacy laws; and

(vii) current Gazettes of list of registered pharmacists and pharmacies.

Forfeiture.

10.-(1) An article seized under these regulations which is found wanting in a material particular thereby constituting a risk to the public shall be forfeited to the Minister.

(2) Without prejudice to the provision of sub. section (1) of this section, a judge of the High Court or a State or a Magistrate may, upon application by a Pharmaceutical Inspector, and after the Court giving notices to such persons and hearing all the parties, direct or order that the article or anything of similar nature found therewith be forfeited to the Minister.

(3) After a person has been convicted of an offence under these regulations, the Court may, order that the article by means of or in respect of which an offence was committed or anything of a similar nature belonging to or in the possession of the person convicted, be forfeited to the Minister.

(4) Where, whether in pursuance of an order of Court or otherwise, any article or thing is forfeited to the Minister under this section, it shall vest in the Minister free of all encumbrances.

(5) The Minister shall, if the article seized is upon examination found to conform to the requirements under these regulations, return the article to the owner or person from whom it was seized.

(6) The Minister shall, if the article seized is upon examination found not to conform to the requirements under these regulations, cause the article to be destroyed or otherwise disposed of as the Minister deems fit.

Offences and Penalties.

11. Any person who:

(a) obstruct or resists a Pharmaceutical Inspector or such other designated officers in the execution of their duties under these regulations;

(b) make a statement which he knows or has reasonable cause to believe to be false or misleading to a Pharmaceutical Inspector or such other designated officer in the course of his duties;

(c) without the authority of a Pharmaceutical Inspector or any other designated officer removes, alters *or* interferes in anyway with an article seized under these regulations;

(d) contravenes any of the provisions of these regulations ;

Shall be guilty of an offence and liable on conviction to imprisonment *for a term* not less than 6 months or fine of N50,000,00 or both.

12. In these Regulations, unless the context otherwise requires 'Article' includes any drug, poison or device, anything used in the manufacture preparation, preservation, packaging, and storing of any drug, poison *or* device and any labelling or advertising material relating to *or* for use in connection with any drug or device;

Interpreta-
tion.

"Council" means Pharmacists Council of Nigeria ;

"Dispensing" means preparations *or* compounding of medicinal products for the immediate use or sale to patients ;

"Inspector" means a pharmacist duly registered and appointed by the Council as such under Regulations 1 and 2 of these Regulations ;

"Inspectorate" means Pharmaceutical Inspectorate Division established under Regulation 1 of these Regulations; and

"Minister" means the Minister charged with responsibility for health.

13. These Regulations may be cited as the Inspection. Location and Structure of Pharmaceutical Premises Regulations, 2005. Citation

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