PREFACE

In view of the passage of the Pharmacy Council of Nigeria (*Establishment*) Act 2022 and the present re-positioning of the Council for more effective regulation and control of the practice of Pharmacy, it is only proper that various components of the Council's activities are clearly explained in perspective. The Council has the responsibility of ensuring that stakeholders are properly guided in accordance with the Act.

Generally, the Council is responsible for the inspection, registration, and licensing of premises where pharmaceutical activities take place. The Council is also saddled with the responsibility of regulating facilities where certain classes of medical devices are manufactured, stored, and sold, among other functions. This informed the update and presentation of these "Guidelines for Inspection, Registration and Licensing of Medical Devices Facilities".

These Guidelines provide detailed information on the procedures for inspection, registration, and licensing of medical devices facilities either as retail, wholesale, distribution, importation, or manufacturing.

All stakeholders should avail themselves of these guidelines to be conversant with the basic requirements and steps for registration with the Pharmacy Council of Nigeria.

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1.0 Introduction

The Pharmacy Council of Nigeria is established by the Pharmacy Council of Nigeria (Establishment) Act 2022 and charged with the following responsibilities among others:

(i) Section 4(i) – Establish and maintain a register of premises used for the manufacture, storage, importation, exportation, distribution, sale and dispensing of drugs, poisons, medicines, and medical devices and accessories;

(ii) Section 23(3) – A person shall not operate premises where drugs, poisons, medicines, medical devices and medical accessories are sold, dispensed, distributed, manufactured, stored, imported or exported unless he has paid the prescribed fees and is duly licensed by the Council.

(iii) Section 16(1)(c) – Register of premises used by pharmacists, pharmacy technicians and patent medicines vendors, or any other person licensed by the Council for the manufacture, production, exportation, importation, stocking for research or any other purposes, storage, distribution, sale or dispensing of drugs and medicines, medical devices and accessories and the provision of other pharmaceutical products shall be entered; and any other register that the Council may require to be kept.

1.1 Definition

Medical Devices in these Guidelines means any device, instrument, apparatus, implement, for in vitro use, material or other similar or related article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- treatment, alleviation of injury;
- medical life support;
- control of conception;
- cleaning, disinfection or sterilization of medical devices;

and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

1.2 Classification of Medical Devices

Class A (Low Risk): Non-invasive devices intended to be used as a mechanical barrier, for compression or for the absorption of exudates only.

Class B (Low–Moderate Risk): Devices intended to be used principally with wounds which have breached the dermis, including devices used for removal or delivery of medications, fluids and nutrition from or into the body.

Class C (Moderate–High Risk)

This classification is in line with their risk level as specified in the World Health Organisation (WHO) Global Model Regulatory framework for medical devices.

Class	Risk	Examples
A	Low	Examination gloves, bandages, gauze, cotton wool, surgical masks, protective gowns, bouffant caps, cleanroom shoe covers, compression sleeves, adhesive wound strips, (thermometers and others,) urine bag, joint support, cervical collar, etc.
B	Low–Moderate	Surgical gloves, infusion sets, syringes, hypodermic needles, intravenous (IV) cannulas, nasogastric tubes, suction catheters, diagnostic test kits, etc.
C	Moderate–High	Condoms – unless with spermicide (in which case, Class D); infusion pumps, neonatal incubators, therapeutic and diagnostic X-ray, lung ventilators, haemodialyzers, anaesthesia equipment.
D	High	Implantable cardioverter defibrillators, pacemakers, breast implants, cardiovascular stents, spinal needles.

Where a medical device belongs to more than one class, the class of the medical device that has the higher risk shall apply.

2.0 Inspection and Monitoring of Medical Devices Facilities

2.1 An intending medical devices facility operator shall apply to the Registrar, Pharmacy Council of Nigeria through the Zonal/State Officer-in-charge of PCN Office in the State where the facility will be located for inspection of the facility before commencement of operation. The application shall state the address of the facility and attach copies of the following documents:

a) Educational qualification of the applicant.
b) List of Medical Devices intended to manufacture, import, store, distribute, wholesale, retail, or sell.
c) Evidence of payment for inspection.

d) In case of manufacturing facility, attach facility design (file master plan).

2.2 Inspection of Medical Devices Facility

All Medical Devices Facility within the mandate of the Pharmacy Council of Nigeria shall be inspected for purpose of registration and licensure of the facilities and revalidation of such licences throughout the supply chain. The Council, through its appointed Inspection Officers shall carry out GXP inspections of the medical devices facilities with respect to location (siting) and structure of the medical devices facility to determine its suitability in line with the global best practices.

2.3 Structure of Medical Devices Facility

Medical Devices facilities shall be made of concrete walls and shall not be less than:

a) 8 square metres for retail;
b) 20 square metres for wholesale;
c) 40 square meters for distributors/importers; and
d) in the case of manufacturing must be of such a size that will ensure good manufacturing practice.

2.4 All inspections of Medical Devices Facilities shall be conducted using appropriate inspection checklists for each category of practice following the prescribed Standard Operating Procedures (SOPs).

2.5 Inspection Timelines for Medical Devices Facilities

(i) Pre-Registration/Facility Inspection

a) For Retail, Wholesale/Distribution and Importation, the pre-registration /facility inspection shall be conducted within two (2) weeks after the Responsible/Authorised Person has applied for the inspection.
b) The report of the inspection and recommendations shall be forwarded to the Registrar within two (2) weeks after the inspection.
c) For Manufacturing facilities, the pre-registration/facility inspection shall be conducted within six (6) weeks after the facility has applied for the inspection and have met all the requirements for the inspection.

(ii) Routine inspection

The timeline for all routine inspection of medical devices facilities (retail, wholesale, distribution, and importation) shall be three (3) weeks after the authorized personnel has applied for inspection.

For medical devices manufacturing facilities, the timeline for regranting of facility certificate inspection shall be six (6) weeks after the application has been received.

The time frame for all routine inspections and re-granting of facility certificate inspection (manufacturing facility) shall be based on the risk rating of the facility as determined from the facility's last inspection outcome.

(iii) Investigative Inspection
Action shall be taken as soon as the petition is received. However, resolution time varies depending on the nature of the petition.

(iv) Monitoring Inspection
The Council shall monitor the operation of the medical devices' facilities to ensure best practices and compliance with these guidelines.

(v) Enforcement Inspections
PCN Inspection Officers shall have the powers to:
a) Conduct surveillance visits on Medical Devices Facilities, and
b) Seal any medical devices facility or premises where any part of these Regulations has been breached.

3.0 Registration and Licensing of Medical Devices Facility

3.1 Registration and Licensing of a New Medical Devices Facility

A new Medical Devices Facility shall be registered after all necessary inspections have been carried out in accordance with the Regulations for Inspection, Registration, and Licensing of Medical Devices Facility.

An authorised personnel shall be eligible to apply for registration of a medical devices facility (retail, wholesale, distribution, importation or manufacturing) provided the authorised personnel has provided a copy of the following document(s):

i) Senior Secondary School Certificate or its equivalent where applicable (minimum requirement).
ii) Relevant Degree certificate such as Pharmacy, Medicine, Biomedical Engineering, Microbiology, Chemistry, Medical Laboratory Science, or any other scientific discipline.
iii) Registration with recognized professional bodies where applicable
iv) Current practicing licence where applicable
v) Certification in GMP, Quality Management, in the case of a medical devices facility engaged in manufacturing, regardless of the class of medical devices.

For the registration of a new medical devices facility (retail, wholesale, distribution, importation, manufacturing), the authorised personnel shall obtain and complete Form BII (Application for Registration or Retention of Medical Devices Facility) from the Zonal/State Offices, which shall be submitted with the following documents to the Registrar, Pharmacy Council of Nigeria through the PCN Zonal/State Offices where the facility is to be located and operated:

i) Application letter addressed to the Registrar to register the medical devices facility;
ii) List of medical devices manufactured, distributed, stocked, or sold;
iii) Evidence of payment of prescribed fees;
iv) Evidence of educational qualification;
v) Registration with recognised professional bodies (where applicable);
vi) Current practicing licence (where applicable);
vii) Letter of appointment in the new Medical Devices Facility (where applicable);
viii) Company's Certificate of Incorporation (where applicable);
ix) Certified Copy of Memorandum and Articles of Association (where applicable);
x) Certified true copies of Particulars of Directors as issued by Corporate Affairs Commission (where applicable);

3.2 Renewal of Certificate of Registration of Medical Devices Facility

A registered Medical Devices Facility shall be due for renewal of its certificate from the first of January every year.

3.2.1 Online Renewal

The Authorised personnel shall pay the prescribed fee and obtain scratch card for renewal of the facility and follow the instruction on the back of the scratch card to submit the application. The application is to be recommended for Registrar's approval within seven (7) working days. Following the Registrar's approval, the electronic copy of the facility certificate will be automatically sent to the designated email of the Authorised personnel. Hard copy of the Medical Devices Facility certificate can be obtained upon request at a prescribed fee.

3.2.2. Change or Variation of Certificate

A registered Medical Devices Facility shall make application to the Registrar, via Form BII, for approval of change, variation or modification in the certificate in respect of authorised personnel name or title, name of facility, ownership of facility, location of facility, category of practice, and additional line for manufacturing or any other change or variation that may affect the licence. Documents to accompany Form BII shall include:

a) Letter to the Registrar specifying the type and reason for change
b) Evidence of change
c) Any legal document that may be required.

The above-listed documents are to be submitted to the PCN State Office where the applicant is domiciled, and licence will be processed within fourteen (14) working days.

3.3 Registration and Renewal of Certificate of Medical Devices Manufacturing Facility

The documents required for registration of Medical Devices Manufacturing Facility are the same as stated in 3.1 above for other pharmaceutical premises.

However, in addition, the following shall be submitted:

a) List of Medical Devices to be manufactured;
b) Organogram;
c) List of staff, qualifications and duties;
d) Factory layout;
e) Production flow chart;
f) List of equipment in production and quality control department;
g) List and sources of suppliers of raw materials and packaging materials;
h) Standard Operating Procedures (SOPs).

Note: All correspondence with the Council must be on the company's letterhead.

4.0 Suspension, Revocation, Withdrawal, or Cancellation of Medical Devices Facility Certificate.

1) When there is a breach of any of the provisions of the Regulations or the Act by the holder of a Facility certificate, the Pharmacy Council of Nigeria, is empowered to suspend, revoke, recall, withdraw, or cancel the licence.

2) Where the Registrar is of the view that a facility certificate should be suspended, revoked, recalled, withdrawn, cancelled, or restored, the holder of such certificate shall, by notice, be required to give reasons within fourteen (14) days of receipt of such notice why the certificate should not be suspended, revoked, recalled, withdrawn or cancelled and if the:

   a) Registrar is satisfied by the reasons so given such certificate shall not be suspended, revoked, recalled, withdrawn or cancelled; or

   b) Reason given is not satisfactory, the Registrar shall notify the holder of the decision to suspend, revoke, recall, withdraw or cancel same and in such case, the holder of the certificate shall appeal to the Council within fourteen days.

5.0 Timeline for Registration and Licensure of Medical Devices Facilities

The following shall be the timeline for registration and licensure of a Medical Device Facility.

1) Upon receipt of the documents at Registry, the medical devices facility shall be issued with a certificate within twenty-one (21) working days provided all documents submitted comply with the requirements for the registration of such Facility.

2) Online renewal application shall be processed within seven (7) working days.

6.0 Right of Appeal

1) Regulatory decision taken or rendered in the course of administering the provisions of these Guidelines, may be appealed against by the aggrieved person in writing within fourteen (14) working days of such decision stating the substance of the complaint and the reliefs sought.

2) The steps and procedures for making appeals shall be in line with the Pharmacy Council of Nigeria Guidelines for Complaints and Appeals Against Regulatory Decisions.

PART V
MISCELLANEOUS PROVISIONS

7.0 General Provisions

1) A request for temporary closure of a Facility shall be for a maximum period of two (2) years and renewal fees shall be paid for the period of the closure after which further request for renewal may not be granted.

2) The failure, refusal or negligence to renew Facility certificate for a maximum period of two (2) years is deemed to be notice to the Council of permanent closure of the Medical Device Facility.

3) The Council shall prescribe or review the fees payable in respect of the registration of the Medical Device Facility.

8.0 Penalties for Late Payment of Fees

1) A Medical Devices Facility that fails, refuses, or neglects to renew its Facility Certificate by the 31st day of March of every year shall, in addition to paying the prescribed renewal fee, pay 50% of the applicable fee as late payment.

2) Where a Medical Devices Facility fails to renew its Facility Certificate by the 31st day of March each year, the Medical Devices Facilities may be sealed.