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NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

CONTROLLED MEDICINES REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 61 of 2021

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1 LFN), 2004

CONTROLLED MEDICINES REGULATIONS, 2021

[7*th Day of July*, 2021] Commencement.

In exercise of the powers conferred on it by sections 5 and 30 of the National Agency for Food and Drug Administration and Control Act (Cap. N1, LFN) 2004 and section 12 of the Food, Drug and Related Products (Registration, Etc.) Act (Cap. F33, LFN) 2004 and all other powers enabling it in that behalf, the Governing Council of the National Agency for Food and Drug Administration and Control with the approval of the Minister of Health makes the following Regulations—

Scope of application.

1. These Regulations shall apply to procedures and processes that will ensure appropriate importation, exportation, manufacturing, storage, warehousing, distribution, inspection, use for medical and scientific purposes, disposal as well as documentation of controlled medicines in Nigeria, to maintain the security and integrity of the product throughout the supply chain.

Prohibition.

2. A controlled medicine shall not be—

(*a*) manufactured, imported, exported, stored, advertised, sold, distributed or used in Nigeria, unless it has been registered in accordance with the provisions of these Regulations ; and

(*b*) manufactured, imported, exported, stored, warehoused, distributed and used in an unsecured manner that will interfere with the integrity of the medicines.

Application for registration.

3.—(1) The registration of controlled medicines shall be in accordance with section 2 of the Food, Drugs and Related products Registration etc. Act (Cap. F33, LFN), 2004.

(2) In addition to the provision of sub-regulation (1) of this regulation an applicant shall obtain—

(*a*) permit or authorization to import ;

(*b*) permit or authorization to clear ; and

(*c*) any other document as may be specified by the Agency.

(3) An applicant shall follow the requirements of the registration process including submission of prescribed documents and payment of appropriate fees as may from time to time be prescribed by the Agency.

Validity of registration.

4.—(1) The registration of a controlled medicine under these Regulations shall, unless cancelled, be valid for a period of 5 years and may be renewed.

(2) Upon renewal, the agency may request local manufacturing of the product.

Suspension or cancellation of certificate of registration, permit or authorisation.

5.—(1) The Agency may suspend or cancel a Certificate of Registration or Permit granted in respect of a controlled medicine where—

(*a*) the grounds on which the controlled medicines were registered were later found to be false or incomplete, or the circumstances under which the controlled medicines were registered no longer exist ;

(*b*) any of the conditions under which the controlled medicines were registered has been contravened ;

(*c*) the standard of quality, safety or efficacy as prescribed in the documentation for registration is not being complied with ;

(*d*) the product has proved to be ineffective for the approved indication ;

(*e*) the premises in which the controlled medicine or part thereof is manufactured, assembled or stored by or on behalf of the holder of the certificate of registration are not in compliance with the requirements of current Good Manufacturing Practice (GMP), as may be determined by the Agency ; or

(*f*) the holder of a Certificate of Registration has given a notice to the Agency in writing of his intention to suspend product registration for a period not exceeding the validity of the certificate of registration.

(2) Where the registration of controlled medicines is suspended or cancelled, the Agency shall order its withdrawal from circulation and shall accordingly cause the suspension, cancellation or withdrawal to be publicised.

(3) Consequent upon the provisions of sub-regulation (1)(*f*) of this regulation, a Holder of Certificate of Registration shall notify the Agency of his intention to resume marketing of a registered controlled medicine and shall submit relevant documents and pay prescribed renewal fee for the product registration, where the product registration has expired.

Importation of controlled medicines.

6.—(1) Controlled medicines may be imported for the following reasons—

(*a*) post-registration importation ; or

(*b*) importation for other purposes.

(2) For post-registration importation, an applicant shall before registration of the product—

(*a*) apply and obtain permit or authorisation to import prior to the shipment ; and

(*b*) apply and obtain permit or authorisation to clear prior to port clearance.

(3) For importation for other purposes—

(*a*) the requirements for importation may be waived at the instance of the Agency for the following reasons—

(*i*) medicines for humanitarian purposes,

(*ii*) donated medicines,

(*iii*) medicines for research purposes,

(*iv*) medicines imported by MDAs, and

(*v*) other purposes as may be prescribed by the Agency ;

(*b*) an applicant shall submit—

(*i*) current annual practicing license of the focal pharmacist, and

(*ii*) a request to the Director-General of the Agency, stating the details of the products, name and strength of the controlled medicines, the brand name of the controlled medicine, quantities and justification for need as well as any other information that may support the application ; and

(*c*) further to obtaining the waiver, the applicant shall—

(*i*) apply and obtain permit or authorisation to import prior to the shipment, and

(*ii*) apply and obtain permit or authorisation to clear prior to port clearance.

Labelling information.

7. The labeling of all controlled medicines shall be in accordance with the Agency's Drug Labeling Regulations.

Storage facility.

8.—(1) Controlled medicines shall be stored in a facility duly registered by the Pharmacists Council of Nigeria (PCN).

(2) Controlled medicines stored in a registered facility shall be—

(*a*) under the supervision of duly licensed pharmacist ;

(*b*) in accordance with the provisions of the current National Drug Distribution Guidelines and current NAFDAC Good Distribution Practices Guidelines and any other document as may be prescribed by the Agency ; and

(*c*) stored in a clearly demarcated and restricted area.

(3) Only the focal pharmacist shall have access to Schedule I medicines at the storage facility.

(4) The focal pharmacist or authorised personnel shall have access to the storage facility for the controlled medicines.

(5) The focal pharmacist shall ensure that medicines are stored in such a manner to ensure safety and maintain their integrity at the dispensing units or service delivery points,

(6) The focal pharmacist shall maintain adequate inventory management system using appropriate inventory tools, including—

(*a*) Disposal of Poisons Book for controlled medicines ;

(*b*) distribution records, in accordance with the Agency's template ; and

(*c*) any other document as the Agency may prescribe.

Distribution.

9. The distribution of controlled medicines shall be the responsibility of an authorised and licensed Pharmacist, in accordance with the provisions of the current—

(*a*) Federal Ministry of Health approved procedures for Narcotics ;

(*b*) NAFDAC Good Distribution Practices Guidelines ; and

(*c*) National Drug Distribution Guidelines.

Procurement, selection and quantification.

10.—(1) Facilities involved in the distribution, storage, handling and utilisation of controlled medicines shall carry out the selection and quantification of the Medicines in line with current—

(*a*) national Guidelines on Estimation of Psychotropic substances and Precursors ;

(*b*) national Guidelines for Quantification of Narcotic Medicines ; and

(*c*) any other document as the Agency may prescribe.

(2) For Schedule 1, controlled medicines—

(*a*) health facilities and pharmacies, approved for distribution of Schedule 1 narcotics, shall procure from Federal Central Medical Store (FCMS) or Zonal Narcotic stores (ZNS) and maintain adequate stock, in line with current Federal Ministry of Health (FMoH) guidelines ; and

(*b*) primary healthcare centres and other service delivery points under the supervision of a focal pharmacist shall procure quantities required from the Health Facilities, Pharmacies, FCMS, ZNS and dispense same to end users.

(3) Facilities shall submit their consumption data to the Agency through the focal pharmacist, using the forms prescribed in the current Guidelines.

Inspection.

11. The Agency shall—

(*a*) undertake relevant inspection of facilities where controlled medicines are handled, manufactured, stored, distributed, dispensed and utilised ; and

(*b*) during inspection, examine the records at any point in the distribution chain up to the service delivery point.

Dispensing.

12.—(1) Controlled medicines shall be dispensed at Community Pharmacies, Primary Health Centres, Primary Health Clinics and Health Post by authorized staff, under the supervision of a licensed pharmacist.

(2) The physician shall be responsible for proper filling in, signing and stamping of the controlled medicine prescription form.

(3) It shall be the responsibility of focal pharmacist to ensure proper handling of controlled medicine.

(4) At the facility level, the focal pharmacist shall be responsible for stocking narcotic and psychotropic medicines, dispensing to the ward or patients in community pharmacies in accordance with prescriptions.

(5) The focal pharmacist shall inspect stock periodically and check the expiration dates of the narcotic and controlled medicines in the pharmacies or health facilities and prepare a monthly statistic of consumption.

(6) The head nurse shall be responsible for keeping of Schedule 1 narcotic medicine for emergency ward supply in a designated cabinet or box for emergency and ensure that proper documentation of consumption at the ward is maintained.

Disposal of controlled medicines.

13.—(1) The Agency shall manage all aspects of the disposal of controlled medicines, including but not limited to damaged, expired or returned medicines.

(2) Damaged, expired or returned Schedule 1 Narcotic drugs shall be separated, valued, documented and returned to the FCMS or ZNS by the health facilities.

(3) Damaged, expired or returned Controlled Medicines (other than Schedule 1 controlled medicines) shall be separated, valued, documented and returned to the Agency's office or Agency's state offices.

(4) The FMOH shall collate all expired and damaged Schedule 1 Narcotic medicines and liaise with the Agency for the disposal.

(5) Healthcare Providers shall make reasonable efforts to retrieve unused controlled medicines from patients or relatives, which shall be returned to the facility for proper documentation and these shall be treated as damaged products.

Offences and Penalties.

14.—(1) A person who contravenes the provisions of these Regulations, commits an offence and is liable on conviction, in the case of—

(*a*) an individual, to imprisonment for a term not exceeding 1 year or to a fine not exceeding ₦800,000.00 or to both ; and

(*b*) a body corporate, to a fine not exceeding ₦5,000,000.00.

(2) Where an offence under these Regulations is committed by a body corporate, firm or other association of individuals, the—

(*a*) director, manager, secretary or other similar officer of the body corporate ;

(*b*) partner or officer of the firm ;

(*c*) trustee of the body concerned ;

(*d*) person concerned in the management of the affairs of the association; or

(*e*) person who purports to act in a capacity referred to in paragraphs (*a*) to (*d*) of this sub-regulation,

is liable to be proceeded against and punished for the offence in the same manner as if the person committed the offence, unless the person proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

Forfeiture after conviction.

15. A person convicted of an offence under these Regulations shall forfeit to the Federal Government—

(*a*) any asset or property constituting proceeds derived from or obtained, directly or indirectly, as a result of the offence ; and

(*b*) any of the person's property or instrumentalities used in any manner to commit or to facilitate the commission of the offence.

Enforcement of these Regulations.

16. The Agency shall be responsible for the enforcement of these Regulations.

Interpretation.

17. In these Regulations—

"*Agency*" means the National Agency for Food and Drug Administration and Control ;

"*Controlled Medicine*" means Narcotics, Psychotropic Substances, Precursors and other nationally controlled medicines ;

"*Distribution*" means movement of products between storage, warehousing and dispensing units or movement between dispensing units and end-users ;

"*FMOH*" means Federal Ministry of Health ;

"*Focal Pharmacist*" means the person, educated and duly licensed by the Pharmacist Council of Nigeria, responsible for the safe keeping of controlled medicines ;

"*Inspection*" means a quality assurance tool used by the Agency to physically review standards of premises, documents and products associated with Controlled substances ;

"*MDAs*" mean ministries, departments and agencies ;

"*Permit or Authorization to Import*" means an official document issued by the Agency to enable persons or body corporate to clear controlled medicines ;

"*Permit or Authorization to Clear*" means an official document issued by the Agency to enable persons or body corporate to import controlled medicines ;

"*Physician*" means person educated, clinically experienced and licensed to practice medicines as usually distinguished from surgery ;

"*Post registration importation*" means the procedure for obtaining permits for importation of controlled medicines for commercial purposes after completion of registration process ;

"*Private health facilities*" means hospitals, community pharmacies or other healthcare facilities where Controlled Medicines are stored or used – not run by government ;

"*Proceeds*" means any property derived or obtained, directly or indirectly, through the commission of the offence ;

"*Restricted access*" means the level of accessibility to sections where controlled medicines are stored or manufactured, this restriction is provided by approved locks, access controls and exclusions with adequate documentations ;

"*Storage*" means the process of storing controlled medicine for future use ;

"*Warehousing*" means a Pharmacists Council of Nigeria licensed premises used by manufacturers, importers, exporters and wholesalers for storing controlled medicines ;

"*Storage facility*" means a space or building designed and used for storing controlled medicines ; and

"*Service delivery point*" means the point of dispensing the medicine to the end users.

18. These Regulations shall be cited as Controlled Medicines Regulations, 2021.

MADE at Abuja this 7th day of July, 2021.

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