NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

CONTROLLED MEDICINES REGULATIONS 2019

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ARRANGEMENT OF REGULATIONS

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (AS AMENDED)
Controlled Medicines Regulations 2019

Commencement

In exercise of the powers conferred on the Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Section 5 and 30 of the National Agency for Food and Drug Administration and Control Act 1993, as amended and of the 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 Honourable Minister of Health, hereby makes the following Regulations.

1. **Scope**

   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, in such a manner as to maintain the security and integrity of the product throughout the supply chain.

2. **Prohibition**

   (1) No controlled medicines shall be manufactured, imported, exported, advertised, sold, stored, distributed or used in Nigeria unless it has been registered in accordance with the provisions of this Regulation.

   (2) No controlled medicines shall be manufactured, imported, exported, stored, warehoused, distributed and used in an unsecured manner that will interfere with the integrity of the medicines.

3. **Application for Registration**

   (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 an applicant shall obtain;
   - (a) permit/authorization to import
   - (b) permit/authorization to clear
   - (c) and 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.

4. **Validity of Registration**

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

(2) A second renewal for another 5 years shall be allowed, following which local manufacturing shall be required.

5. **Suspension or cancellation of Certificate of registration, permit or authorization.**

(1) The Agency may suspend or cancel any Certificate of Registration of a controlled medicine

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

(b) any of the conditions under which the controlled medicines was 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 in-effective for the approved indication(s);

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

(f) The Certificate of Registration Holder has given a notice to the Agency in writing of any intentions 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 the withdrawal from circulation of that and shall accordingly cause the suspension, cancellation or withdrawal to be published.

(3) Consequent upon the provisions of Regulations 5(1) (a), a Certificate of Registration Holder may notify the Agency of his intention to resume marketing of a registered controlled medicine and shall submit relevant documents and pay the prescribed renewal feed for the product registration where the product registration has expired.

6. **Importation of Controlled medicines**

(1) Controlled medicines may be imported for the following purposes;

(a) post-registration importation

(b) importation for other purposes

(2) **Post-registration importation**

(a) Further to the registration of the product, an applicant shall:

(i) apply and obtain permit/authorization to import prior to the shipment,

(ii) apply and obtain permit/authorization to clear prior to port clearance.

(3) **Importation for other purposes**

(1) The requirements for importation of controlled medicines for others purposes may be waived at the instance of the Agency for the following purposes;

(a) medicines for humanitarian purposes,

(b) donated medicines,
(c) medicines for research purposes, and
(d) medicines imported by MDAs
(e) other purposes as may be prescribed by the Agency

(2) An applicant shall submit a request to the Director General NAFDAC, stating the details 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.

(3) Further to obtaining the waiver, the applicant shall;
(a) apply and obtain permit/authorization to import prior to the shipment,
(b) apply and obtain permit/authorization to clear prior to port clearance.

7. **Labelling Information**

The labelling of all controlled medicines shall be in accordance with the provisions of the current NAFDAC Drug Labelling Regulations.

8. **Storage facility**

(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.
(c) stored in a clearly demarcated area.
(d) restricted to unauthorized persons to the designated storage facility.

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

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

(5) Authorized personnel shall ensure that medicines are stored in such a manner to ensure safety and maintain their integrity at the dispensing units/service delivery points,

(6) The authorised personnel 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)
(c) any other document as the Agency may require.

9. **Distribution**

(1) The distribution of controlled medicines shall be the responsibility of an authorised and licensed Pharmacist, in accordance with the provisions of the current,
(a) National Drug Distribution Guidelines,
(b) NAFDAC Good Distribution Practices Guidelines, and

(c) Federal Ministry of Health approved procedures for Schedule 1 Narcotics.

10. **Procurement, Selection and Quantification**

(1) Facilities involved in the distribution, storage, handling and utilization 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.
   (c) Any other document as the Agency may require.

(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
   (b) primary healthcare centres and other service delivery points shall procure quantities required from the Health Facilities, Pharmacies or FCMS/ZNS and dispense same to end users.

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

11. **Inspection**

(1) The Agency shall undertake relevant inspection of facilities where controlled medicines are handled, manufactured, stored, distributed, dispensed and utilised.

(2) The Agency shall during its inspection examine the records at any point in the distribution chain up to the Service delivery point.

12. **Dispensing.**

(1) Controlled medicines shall be dispensed at the Primary Health Centres, primary health clinics and health post by authorized staff under the supervision of a licensed pharmacist.

(2) The physicians 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 the controlled medicine.

(4) At the facility level, the focal pharmacist shall be responsible for stocking narcotic and psychotropic medicines, dispensing to the ward and patient 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 statistics of consumption.

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

13. **Disposal of Controlled Medicines**

(1) NAFDAC will 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 /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 NAFDAC 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/ relatives, which shall be returned to the facility for proper documentation. These shall be treated as damaged products.

14. **Penalty.**

(1) Any person who contravenes any of the provisions of these Regulations shall be guilty of an offence and liable on conviction. In case of :

(a) an individual, to imprisonment for a term not exceeding one year or to a fine not exceeding N50,000 or to both such imprisonment and fine; and

(b) a body corporate, to a fine not exceeding N100, 000.

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

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

(b) partner or officer of the firm or

(c) trustee of the body concerned ;or

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

(e) person who was purporting to act in a capacity referred to in paragraphs (a) to (d) of this regulation, is severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if he had himself committed the offence, unless he proves that the act or omission constituting the offence took place without his knowledge, consent or connivance.

8. **Forfeiture after conviction**

(1) 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;

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

(2) In this section, "proceeds" means any property derived or obtained, directly or indirectly, through the commission of the offence.

15. **Interpretation**

In these Regulations, unless the context otherwise requires;

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

"Controlled Medicine" means Narcotics, Psychotropic Substances and Precursors.

"Distribution" means movement of products between storage/warehousing and dispensing units and movement between dispensing units and end-users.

"FCMS" means Federal Central Medical Stores.

"FMOH" means the Federal Ministry of Health.

"Focal Pharmacist" means the person 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.

'MDA' means ministries, departments and agencies.

"Permit/Authorization to Import" means an official document issued by the Agency to enable persons or body corporate to import controlled medicines.

"Permit/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 or facilities where Controlled Medicines are stored or used – not run by government

"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 commercial building 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.

"Service Delivery Point" means the point of dispensing the medicine to the end users.

"ZNS" means Zonal Narcotics Stores.

16. **Citation**

These Regulations may be cited as **Controlled Medicines Regulations 2019.**

MADE at Abuja this……day of……2019.

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Inuwa Abdulkadir Esq
Chairman Governing Council
National Agency for Food and Drug Administration and Control (NAFDAC)