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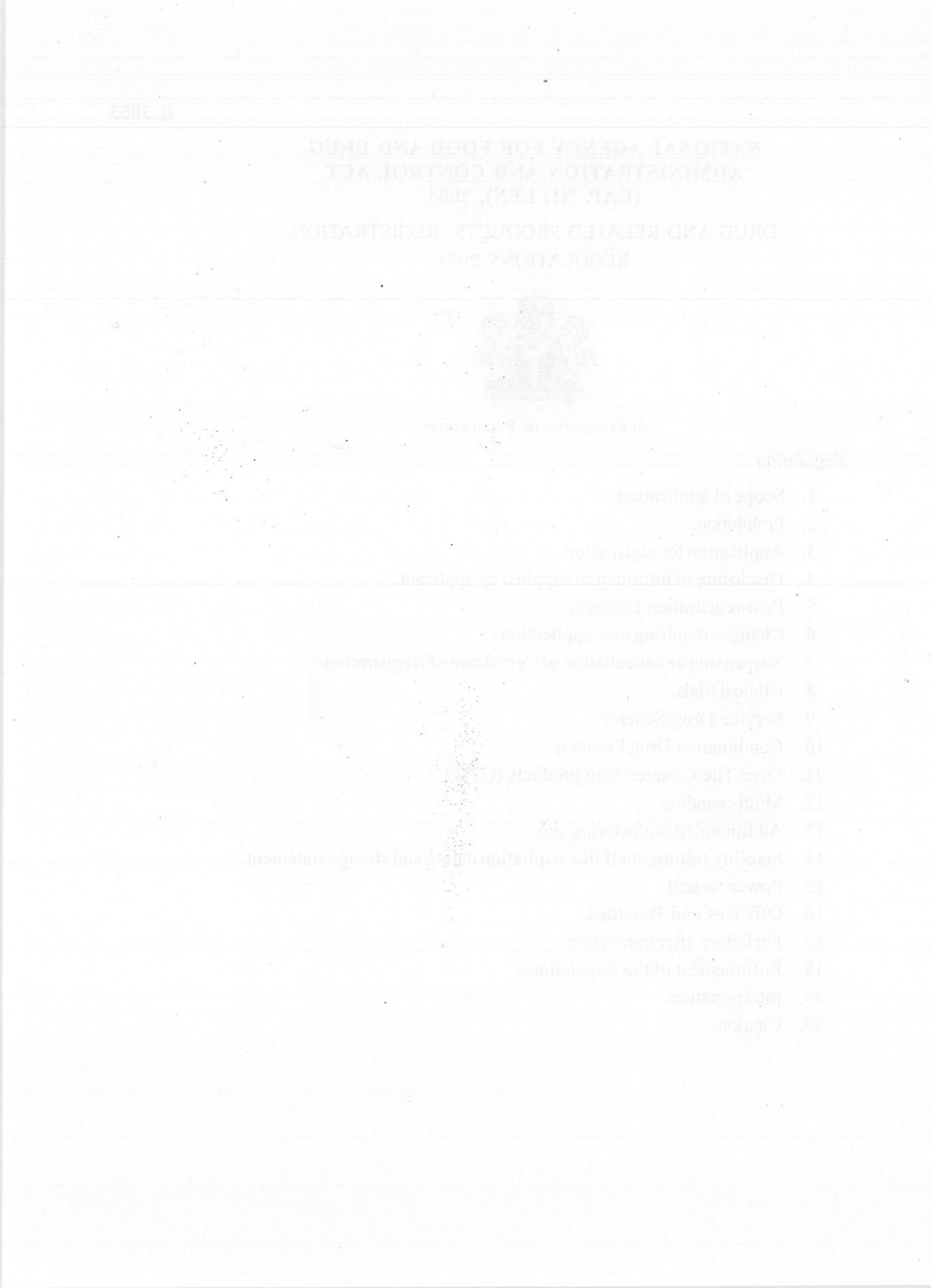
NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL ACT (CAP. N1, LFN), 2004

DRUG AND RELATED PRODUCTS REGISTRATION REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :



S. I. No. 64 of 2021

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

DRUG AND RELATED PRODUCTS REGISTRATION REGULATIONS, 2021

[*7th 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—

1. These Regulations shall apply to registration of drugs and related products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria. Scope of application.

2.—(1) A drug product shall not be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered in accordance with the provisions of these Regulations. Prohibition.

(2) Notwithstanding the provisions of sub-regulation (1) of this regulation, the National Agency for Food and Drug Administration and Control (NAFDAC) may grant a permit for the importation or manufacture of a sample of drug product for the purpose of—

(*a*) registration ;

(*b*) clinical trial ;

(*c*) Service Drug Scheme ;

(*d*) use in emergency situation resulting from disease outbreaks ; and

(*e*) donation for humanitarian interventions.

(3) The importation or manufacture of drug product for the purpose under sub-regulation (2) of this regulation shall be in accordance with the conditions specified in the permit granted by NAFDAC.

(4) A person to whom a certificate of registration has been issued under these Regulations shall not lend, hire, sell, transfer or otherwise dispose of the certificate of registration to any other person except with the approval of the Agency.

Application for Registration.

3.—(1) Application for the registration of a drug product shall be made by submitting a complete application form, accompanied by relevant documents as the Agency may, from time to time, prescribe and shall—

(*a*) contain the particulars and description of the drug product, in respect of which the application is made ; and

(*b*) be accompanied by such fee as the Agency may, from time to time, prescribe.

(2) The drug product particulars and description shall be detailed enough to consist of all administrative and technical information with a view to allowing the Agency make informed decision about the product.

(3) The Agency, in considering an application—

(*a*) may ask the applicant to supply information as it may require to enable it reach a decision on the application ;

(*b*) shall satisfy itself that there is need to have the drug product registered in Nigeria ; and

(*c*) may register the drug product in accordance with the provisions of Food, Drug and Related Products (Registration etc.) Act cap F33 LFN 2004.

(4) The registration of a drug product under these Regulations shall, unless it is cancelled, be valid for a period of 5 years and may be renewed.

(5) The Agency shall, from time to time, publish the list of registered drugs or drug products on the Agency's official website, notifying the registration of a drug product.

(6) The Agency may refuse or reject an application for registration, where—

(*a*) it is discovered that the method, facilities or controls used in the manufacture, processing and packaging of the drug product are inadequate to ensure and consistently preserve its identity, strength, quality and purity ;

(*b*) laboratory report for the product is unsatisfactory ;

(*c*) good manufacturing practice inspection report is unsatisfactory ; or

(*d*) product labeling contravenes the Agency's Drug and Related Product Labelling Regulations of the Agency.

Disclosure of information supplied by applicant.

4. A person shall not disclose information supplied to the Agency pursuant to Regulation 3 of these Regulations, except—

(*a*) with the written consent of the person who supply the information ;

(*b*) in accordance with the directive of the Agency ; or

(*c*) for the purpose of a proceeding under these Regulations.

Post-registration changes.

5.—(1) Except as prescribed in these Regulations, no change shall be carried out in relation to terms and conditions under which a drug product was registered without a prior approval of the Agency.

(2) Every application for change to an approved product shall be submitted to the Agency, describing in detail the changes to be carried out in accordance with the Variation Guidelines or any other requirements as may be specified by the Agency.

(3) Depending on the type of change, the Holder of Certificate of Registration shall apply to the Agency for the change, through a notification or variation application along with the payment of the prescribed fee as may be determined by the Agency or by a way of annual notification.

(4) As may be determined by the Agency, a post-registration change may be accomplished through—

(*a*) annual notification ;

(*b*) immediate notification ;

(*c*) minor variation ; or

(*d*) major variation.

(5) Where a change is to be effected, the Holder of Certificate of Registration shall not distribute the drug product unless the—

(*a*) effect of the change has been duly assessed and duly approved by the Agency ; and

(*b*) product label has been revised to reflect the change, where applicable.

(6) Changes that may have minimal or no potential to have an adverse effect on the identity, strength, quality, purity, or potency of a drug product may be implemented prior to notifying the Agency.

Changes requiring new application.

6. For the purpose of these Regulations, the following changes shall require a new application—

(*a*) change of the Active Pharmaceutical Ingredient (API) to a different API ;

(*b*) inclusion of an additional API in a multi-component product ;

(*c*) removal of one API from a multi-component product ;

(*d*) change in the strength of one or more APIs ;

(*e*) change from an immediate release product to an extended or delayed-release dosage form or *vice versa* ;

(*f*) change from a liquid to a powder for reconstitution or vice versa ;

(*g*) changes in the route of administration ; or

(*h*) any other changes as may be determined by the Agency.

Suspension or cancellation of Certificate of Registration.

7.—(1) The Agency may suspend or cancel the registration of a drug product, where—

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

(*b*) any of the conditions under which the drug product 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 ;

(*e*) the premises in which the drug product or part of the drug is manufactured, assembled or stored on behalf of the Holder of 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 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 a drug product is suspended or cancelled, the Agency shall order the withdrawal from circulation of the drug product and shall accordingly cause the suspension, cancellation or withdrawal to be published.

(3) Where a Certificate of Registration is suspended or cancelled pursuant to the provisions of sub-regulations (1) (*a*) of this regulation, a Holder of such Certificate of Registration may notify the Agency of his intention to resume marketing of a registered product and shall submit relevant document and pay the prescribed renewal fee for product registration, where the product Registration Certificate has expired.

Clinical Trials.

8.—(1) A person shall not, in the course of his business—

(*a*) import or supply a drug product ;

(*b*) procure the importation or supply of a drug product ; or

(*c*) procure the manufacture or assembly of a drug product, for the purpose of a clinical test, unless the person is a holder of a valid Clinical Trial Certificate of Authorisation and the trial is to be carried out in accordance with the terms of the certificate and the provisions of any Regulation in force.

(2) Application for a clinical trial shall be made to the Agency in such form and manner as may be prescribed by the Agency.

Service Drug Scheme.

9.—(1) A person shall not, in the course of his business import or supply a drug product or procure the importation or supply of a drug product for the purpose under the Service Drug Scheme, unless the person is a holder of a valid Import Permit issued by the Agency for the purpose.

(2) Application for importation of a drug product under Service Drug Scheme shall be made to the Agency, in such a manner as may be prescribed by the Agency.

(3) The use and sale of drug products under the Service Drug Scheme shall be restricted to the receiving premises as indicated on the Permit.

Combination Drug Products.

10.—(1) Combination Drug Product, as a Fixed Dose Combination (FDC) or Co-packaged Drug Product, shall not be registered unless—

(*a*) monograph for such product exists in any of the officially recognised pharmacopoeia ; or

(*b*) suitability of such information as determined by the Clinical Trial Unit of the Agency or other relevant body of experts appointed by the Agency, established that each of the components contribute to the overall claimed effects of the product and the dosage of each component, amount, frequency, duration, is such that the combination is safe and effective for a significant patient population requiring such concurrent therapy as defined in the labeling for the drug.

(2) The shelf life and expiration date, regarding co-packaged drug product shall be determined by the component of the co-packaged product with the shortest shelf life.

(3) Labeling information regarding generic product of an FDC or co-packaged product shall be in compliance with the agreed Product Information (PI) for the innovator or referenced combination drug product as may be determined by the Agency.

(4) Provision for periodic safety update and risk management plan shall be made for any combination product not referenced in any of the officially recognised pharmacopoeia.

Over-The-Counter drug products (OTC).

11.—(1) A product shall not be registered as an Over–The-Counter drug product unless—

(*a*) it is demonstrated that there is an established efficacy and safety of use among the relevant population ;

(*b*) there is no specific safety concern limiting its safe use without medical assistance ;

(*c*) indication for its use is easily diagnosable and self-limiting as the case may be ; and

(*d*) pack presentation is tailored to the approved duration and indication of use.

(2) Product switch from Prescription-only-Medicine to Over-the-Counter drug is not permitted unless it is approved by the Agency.

(3) Upon satisfying other requirements for drug product registration, an applicant shall provide adequate information in a format as may be prescribed by the Agency supporting the status of the product as generally safe, effective and adequately labeled to support its use without a prescription.

(4) A drug product may be registered as an OTC on the basis of its OTC status from its country of origin, where, it has been marketed as an OTC for a minimum of 5 continuous years in the country of origin and in sufficient quantity or as may be required by the Agency.

Multi-branding.

12. A person shall not import the same drug product from the same manufacturer under different brand names.

(1) Notwithstanding the provision of regulation 11(1) of these Regulations, a drug product which can be registered under different marketing categorization as Over-The-Counter drug as well as Prescription Only Medicine on the basis of differences in strength may be exempted.

Additional manufacturing site.

13. A person shall not import a drug product from more than one manufacturing site unless the—

(*a*) company is a recognised multinational company based on criteria as determined by the Agency ; or

(*b*) registration of the additional manufacturing site is a subject of drug product registration under collaborative registration procedure with other national, regional or international organizations recognised by the Agency.

Stability testing. shelf life. expiration dating and storage statement.

14.—(1) For the purpose of establishing shelf life and determining appropriate storage condition for a drug or drug product, a drug or drug product intended to be marketed in Nigeria shall under general case be tested under long term and accelerated stability conditions prescribed for climatic Zone IVB.

(2) Notwithstanding the requirement in sub-regulation (1) of this regulation, drug or drug product which is thermolabile and hence requires temperature-controlled storage, shall be tested according to long term conditions simulating the real conditions of storage.

(3) Expiry date shall be established for each drug or drug product by adding the determined shelf-life to the date of manufacture of drug or drug product batches tested under stability programme.

(4) A storage statement shall be established for the label based on the stability evaluation of the product and where applicable, specific instructions shall be provided, particularly for drug product that cannot tolerate freezing and terms such as "ambient conditions" or "room temperature" shall be avoided.

(5) For drug or related drug product not requiring temperature-controlled storage, the labeling as demonstrated by the stability of the product shall be "Store below 300C".

(6) Ancillary cautionary storage statements may be required as shall be determined based on results from Accelerated Stability studies.

Power to seal.

15. The Agency shall have power to seal up any premises used or being used in connection with any offence under these Regulations until such time as the regulated product is removed or such reasonable time as the Minster may determine.

Offences and Penalties.

16.—(1) Any person who contravenes any of the provisions of these Regulations commits an offence and 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 every—

(*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 that 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.

17. 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.

Interpretation.

18. In these Regulations,—

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

"*Certificate of Registration*" means a document describing the particulars and conditions under which a product is registered and indicate the assigned NAFDAC Reg. No. for a product ;

"*Collaborative Registration Procedure*" means an accelerated registration procedure for drug products registered under World Health Organization Prequalification of Medicines Programme (PQP), the West African Health Organization's Joint drug product assessment procedure and by Stringent Regulatory Agencies (SRAs, facilitated by World Health Organization) through improved information sharing ;

"*Co-packaged drug product*" means product that contains two or more separate drugs in their final dosage forms that are intended to be used together for a common or related therapeutic purpose and that are contained in a single package or unit ;

"*Drug*" includes any substance of vegetable, animal or mineral origin, or any preparation or admixture thereof manufactured, sold or advertised for use in—

(*a*) the diagnosis, treatment, mitigation or prevention of any disease, disorder, abnormal physical state or the symptom thereof, in man or animal ;

(*b*) restoring, correcting or modifying organic functions in man or in animal ;

(*c*) disinfection or the control of vermin, insects or pests ; or

(*d*) contraception ;

"*Expiry date*" means the date given on the individual container, usually on the label, of a product up to and including which the Active Pharmaceutical Ingredient (API) and Finished Pharmaceutical Product (FPP) are expected to remain within specifications, if stored correctly. It is established for each batch by adding the shelf-life to the date of manufacture ;

"*Fixed Dose Combination product*" means a product consisting of combination of two or more active ingredients in a single dosage form, the active ingredients usually combined in a fixed ratio ;

"*Generic or Common name*" means the official Non-Proprietary name of a drug product or substance assigned by National or International bodies such as International Non-propriety Name (INN) secretariat ;

"*Generic product*" means pharmaceutically equivalent, equivalent in dosage form, product in dosage, strength, route of administration, quality, or pharmaceutically alternative products that may or may not be therapeutically equivalent to the innovator product. Therapeutically equivalent products are interchangeable ;

"*Minister*" means the minister charged with the responsibility of matters relating to health ;

"*Multinational Company*" means a corporate organization that owns or controls production of goods or services in at least one country other than its home country but is managed from one (home) country and such companies have offices or factories in different countries and usually have a centralized head office from where global management is coordinated ;

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

"*Registered product*" means a drug or drug related product which has been approved by the Agency and assigned a NAFDAC Reg. No. to be manufactured, imported, exported, sold, distributed or advertised ; and

"*Service drug*" means medicines that are not readily available in Nigerian market but are needed to meet varying unique individual health needs of patients and clients within the community.

Enforcement of these Regulations.

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

Citation.

20. These Regulations shall be cited as the Drugs and Related Products Registration Regulations, 2021.

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

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