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

DRUG AND DRUG PRODUCTS (REGISTRATION) REGULATIONS 2018

COMMENTS ARE WELCOMED FROM STAKEHOLDERS WITHIN 60 CALENDAR DAYS (ending 29th August, 2018).
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ARRANGEMENT OF SECTIONS

Commencement:

In exercise of the powers conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by Sections 5 and 30 of the NAFDAC Act Cap N1 LFN 2004 and Section 12 of the Food, Drugs and Related Products (Registration, Etc.) Act Cap F33 LFN 2004 and of all 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 Honorable Minister of Health hereby makes the following Regulations:-

1. Scope

All drug products manufactured, imported, exported, advertised, sold, distributed or used in Nigeria shall be registered in accordance with the provisions of these Regulations.

2. Prohibition

(1) No drug product shall be manufactured, imported, exported, advertised, sold, distributed or used in Nigeria unless it has been registered in accordance with the provisions of these Regulations.

(2) Notwithstanding the provisions of Regulations 2 (1) of this Regulation, the National Agency for Food and Drug Administration and Control 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
(e) Donation for humanitarian interventions

and the importation or manufacture shall be in accordance with the conditions specified in the permit.

3. Application for registration

(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;
(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 in sufficient details as may be required to allow the Agency make informed decision about the product

(3) The Agency, in considering an application-

(a) may ask the applicant to supply such other 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.

(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 cancelled earlier, be valid for a period of five years and may be renewed.

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

The Agency may refuse or reject an application for registration if:

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

(b) laboratory report for the product is unsatisfactory

(c) good manufacturing practice inspection report is unsatisfactory

(d) product labeling contravenes the Drug and Drug Product Labeling Regulations 2018

4. Disclosure of information supplied by applicant

(1) No person shall disclose an information supplied to the Agency in pursuance of Regulations 3 of these Regulations except-

(e) with the written consent of the person who supplied the information; or

(a) in accordance with the directive of the Agency; or

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

5. Post-registration changes

(1) Except as prescribed in these Regulations, no change shall be carried out to the 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.

(3) Depending on the type of change, the Certificate of Registration holder shall apply to the Agency about the change through a 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

(d) Major Variation

(5) Where a change has been effected with the approval of the Agency, the Certificate of Registration holder shall not distribute the drug or drug product unless:

(a) The effect of the change has been duly assessed

(b) The product label has been revised to reflect the change.

(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.

6. Changes requiring new application

For the purpose of these Regulations, the following changes herein listed (or as may be prescribed by the Agency) shall require a new application:

(1) Change of the Active Pharmaceutical Ingredient (API) to a different API

(2) Inclusion of an additional API in a multicomponent product

(3) Removal of one API from a multicomponent product

(4) Change in the dose and/or strength of one or more APIs

(5) Change from an immediate release product to an extended or delayed-release dosage form or vice versa

(6) Change from a liquid to a powder for reconstitution or vice versa.

(7) Changes in the route of administration

(8) Change in manufacturing source other than additional manufacturing site for certain Certificate of Registration holder as may be determined by the Agency

7. Suspension or cancellation of certificate of registration

(1) The Agency may suspend or cancel the registration of a drug product if-

(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(s);

(e) the premises in which the drug product 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 drug product is suspended or cancelled, the Agency shall order the withdrawal from circulation of that drug product and shall accordingly cause the suspension, cancellation or withdrawal to be published.

(3) Consequent upon the provisions in Regulations 7(1)(a), a Certificate of Registration holder 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.

8. Clinical trials

(1) No person shall, in the course of his business-

(a) import or supply a drug product, or

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

(c) procure the manufacture or assembly of a drug or drug product, for the purpose of a clinical test, unless he is a holder of a valid Clinical Trial Certificate of Authorization 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.

9. Service drug scheme

(1) No person shall, 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 he is a holder of a valid import permit issued by the Agency for that purpose.

(2) Application for importation of a drug product under Service 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 Services drug scheme shall be restricted to the receiving premises as indicated on the permit.

10. Combination Drug Products (Fixed Dose Combination; FDC, and Co-packaged drug product)

(1) No Combination Drug Product (as a Fixed Dose Combination or Co-packaged Drug Product) shall be registered unless:

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

(b) suitability of such information as determined by the Clinical Trial Unit of the Agency and/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 dating regarding co-packaged drug product shall be determined by the component of the co-packaged product with the shortest shelf life.

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

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

11. Over-the-counter drug products (OTC)

(1) No product shall 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.

(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 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 if 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.

12. Multi-branding

(1) No person shall import the same drug product from the same manufacturer under different brand names.

(2) Notwithstanding the provision in Regulation 11(1), 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 pack size presentation may be exempted from Regulation 11(1).

13. Additional Manufacturing site

(1) No person shall import a drug product from more than one manufacturing site unless;

(a) the company is a recognized multinational company based on criteria as determined by the Agency.

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

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

(1) For the purpose of establishing shelf life and determining appropriate storage condition(s) 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 13.1(a), drug or drug product which is thermobile 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. Where applicable, specific instructions shall be provided, particularly for drug product that cannot tolerate freezing. Terms such as "ambient conditions" or "room temperature" must be avoided.

(5) In general, for drug and drug product not requiring temperature controlled storage, the labeling as demonstrated by the stability of the product shall be "Store below 30^0C".

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

15. 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 50,000 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.

16. 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.

17. Interpretation

In this Regulations, unless the context otherwise requires -

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

"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" or "Drug product" 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 usual combined in a fixed ratio;

"Generic/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; 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 for matters relating to health.

"**Multinational Company"** A 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. Such companies have offices and/or factories in different countries and usually have a centralized head office from where global management is coordinated.

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

"Registered product" 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.

18. **Repeal**

(1) The Drugs and Related Products (Registration, Etc.) 1993 is hereby repealed.

(2) The repeal of these Regulations specified in Regulations 21(1) shall not affect anything done or purported to be done under the repealed Regulations

19. **Citation**

These Regulations may be cited as the Drugs and Related Products (Registration) Regulations, 2018.

MADE at Abuja this …….day of ……..2018

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