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

DRUG AND RELATED PRODUCT LABELLING REGULATIONS, 2021

ARRANGEMENT OF REGULATIONS

Regulation :

S. I. No. 65 of 2021

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

DRUG AND RELATED PRODUCT LABELLING 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—

Scope of application.

1. These Regulations shall apply to all labelling of drug and related products, manufactured, imported, exported, sold, distributed or used in Nigeria.

Prohibition.

2. A person shall not manufacture, import, export, distribute, advertise, display for sale or use any drug or drug product unless it is labelled and it is in accordance with these Regulations.

Reference to national or international bodies.

3. Label of a drug or drug product shall not make reference either directly or indirectly, to a national or international body, except as permitted, prescribed or specified by the Agency.

Labelling information.

4.—(1) All information required to be indicated on the label of a product, shall be prominent, legible and distinct.

(2) Every statement shall appear in font size and style type, which is adequate for clarity and on sufficient contrasting background without obscuring designs or vignettes or crowding within printed or graphic matter.

(3) All information for drug or related product shall be in English Language, and may include any other languages.

(4) Labelling shall be informative and accurate.

(5) Labelling shall not be false or misleading.

(6) All information and statements required by these Regulations shall appear on the part or panel of the label which is presented or displayed under customary conditions of purchase.

(7) The label space shall not be used to present information, statement or graphics not required by these Regulations in such a manner that will make the label space insufficient for the prominent placing of such information or statements required under these Regulations.

(8) Special labeling requirements and drug safety information shall be clearly stated.

Name and address of Manufacturer, Holder of Certificate of Registration, Packer on label.

5.—(1) The label of a drug shall be conspicuous, indicating the name and manufacturing location, address of the manufacturer, and the name of the holder of certificate of registration.

(2) Where a drug is manufactured under a contract of manufacturing arrangement, the name and manufacturing address shall be indicated by a phrase that reveals the connection with the entity such as "Manufactured by....., for.....", 'Manufactured for.....by.....", or any other wording that expresses the facts.

(3) The name of the person represented as manufacturer under regulations 5(1) and 5(2), may be the same as either the name of establishment under which the entity is registered at the time the labelled product is manufactured or the registered name of the parent, subsidiary or affiliated company, where the related companies are under common ownership and control, the corporate name may be followed or preceded by the name of the particular division.

(4) The site address of the manufacturer of a drug shall be complete on labels of all packaging components, for example Primary, Secondary and Tertiary), unless the immediate container of the drug contains 5ml (or equivalents) or less of the drug product, in which case the address needs not be shown on the inner label.

Display of generic and brand name.

6.—(1) The packaging components of a drug product shall bear the name, active ingredients, strength and dosage form of the drug.

(2) Where a drug is branded, the generic (common) and brand (proprietary) names shall be reflected on all packaging components (primary, secondary and tertiary).

(3) The name shall prominently appear on the principal display panel of the package to aid accurate identification.

(4) To satisfy the requirement for prominence, the generic or common name shall be printed in letters that are as large and visible as those of the brand (proprietary) on both the principal display panel and other labeling components.

(5) Where a drug contains a single active ingredient, the common or generic name shall appear in conjunction and in close proximity to the brand name, if any, of the drug.

(6) The generic or common name shall appear directly below the brand or proprietary name on all labeling components except in a running text of pack insert, where generic or common name is required to appear at least once in the same font and style, type, size as the brand proprietary name.

(7) The representation of the generic or common name on principal display panel and all labeling components shall be in the format; name, followed

by pharmaceutical dosage form, the compendia standard, if applicable and the strength (mg or g) for example "XYZ tablets 200mg".

(8) A product shall not be labeled or designated with claim of compliance with official compendia standard, except it complies with the specifications of the official compendia.

(9) Where a drug contains more than one active ingredient, all the common names shall appear on the principal display panel of the drug, unless the drug is packaged in a container too small to bear the information, then it shall appear on the information panel.

(10) In the case of a drug product containing two or more active ingredients, if the label indicates the brand (proprietary) name and there is no common name corresponding to such combination, the quantitative ingredient information required on the label by these Regulations shall be placed conspicuously on the panel. The prominence of the quantitative ingredient information shall bear a reasonable relationship to the prominence of the brand name.

(11) Where the generic or common name is required to accompany or to be used in association with the brand (proprietary) name in a running text, the common or generic name shall be placed in direct conjunction with the brand name.

Declaration of net content of drug.

7.—(1) The outer label of a drug shall indicate the net content of the drug in the container in terms of unit weight, measure or number.

(2) The declaration of net content of drug in tablet, capsule, ampoule, vial or other unit dosage form shall be expressed in numerical count; the declaration of net content for DRUG in other dosage forms shall be in terms of weight if the drug is solid, semi-solid, or viscous, or in liquid measure or volume, if the drug is liquid.

(3) Declaration of weight of the contents shall be expressed in terms of metric units *i.e.* kilogram, gramme, and subdivisions.

(4) Declaration of liquid measure or volume of the contents shall be expressed in the liter and milliliter, cubic centimeter and subdivisions.

(5) Declaration of net content of a co-packaged drug product shall state the quantity of each component in conjunction with other components of the co-pack using the plus sign (+) with the statement of quantity enclosed within brackets and "Co-pack" or "Combipack" preceding the statement of content, for example: 1 Co-pack (3 tablets +2 capsules) or 1 Combipack (1 vial + 5ml ampoule +1ml ampoule); if there are more than one co-packs in a pack, the number of co-packs within a pack shall be described in numerical counts such as 2 x 1 Co-pack.

Brand name or Trademark.

8.—(1) The brand name or trade mark shall be displayed on the label and shall not give a wrong impression of the nature, quality or substance of the drug product.

(2) Where the brand name or trade mark registration is in conflict with any Regulations or requirements of the Agency. the latter shall supersede and prevail.

(3) The brand name of a drug product shall not sound or look like already registered drug product.

(4) Where a drug product has been registered under a brand name or as a range of drug products with similar active ingredients, at least one of the active ingredients must be common to the parent and the brand name shall bear a differentiating suffix.

Registration number assigned by the Agency.

9.—(1) The outer and inner labels of a drug shall clearly show the registration number of the Agency (NAFDAC REG. NO.) assigned to it as indicated on the certificate of registration in a manner prescribed by the Agency.

(2) Where a drug product has tertiary, secondary and primary packaging materials and the content of a unit pack is reasonably considered to be dispensed or sold to an end-user as a whole or is for a single use, the NAFDAC REG. No. shall be shown on the tertiary and secondary packaging materials only.

Identification mark.

10.—(1) Where tablets, capsules, caplets and similar dosage forms bear identification marks the identification marks shall be traceable to the certificate of registration holder or the manufacturer of the drug product.

(2) The following classes of drug products are exempted from the requirements in sub-regulation (1)—

(*a*) drug products intended for use in a clinical trial investigation or bio-equivalence studies ;

(*b*) radiopharmaceutical drug products ;

(*c*) drug products with product size, shape, physical characteristics which make imprinting technologically infeasible or impossible ; and

(*d*) drug administered solely in controlled healthcare settings.

(3) Exemptions request shall be made in writing to the Agency.

Labelling of dispensing measure.

11. All packages for oral pediatric liquid drug products, shall have included in them, an appropriate measuring device graduated as applicable.

Package insert.

12. All prescription, only drug shall be accompanied by a package insert with relevant information as required in these Regulations and any other information as may be required by the Agency.

Labelling of parenteral preparations.

13.—(1) The Labelling of injectable drug products shall provide adequate information to health care practitioners and other users to ensure safe and

proper use of the therapeutic agent and where all the information required may not be contained on the immediate container, they shall be included in the package insert.

(2) The Labelling shall state the following—

(*a*) the name of the product ;

(*b*) percentage content of the drug in liquid preparations ;

(*c*) amount of active ingredients (for drug powder form) ;

(*d*) volume of liquid to be added for reconstitution of the drug powder ;

(*e*) the route of administration ;

(*f*) storage conditions ;

(*g*) batch or lot number ;

(*h*) manufacture and expiry dates ;

(*i*) the full name and address of the manufacturer ;

(*j*) preparations intended for use in dialysis, haemofiltration, irrigation or any other use, shall bear the statement "Not intended for intravenous injection"; and

(*k*) injection for veterinary use shall be so labeled, including the withdrawal period.

Declaration of non-nutritive sweeteners.

14.—(1) The labels of all packaging components for Over-The-Counter products containing an approved non-nutritive sweetener as an inactive ingredient, shall bear a conspicuous declaration as to the identity and quantity of the non-nutritive sweetener in milligram per dosage unit and shall also bear boldly and conspicuously, any precautionary warnings for the non-nutritive sweetener as may be prescribed by the Agency.

(2) The package inserts providing information concerning prescription drug containing an approved non-nutritive sweetener as an inactive ingredient shall bear a conspicuous declaration as to the identity and quantity of the non-nutritive sweetener in milligram per dosage unit and shall also bear boldly and conspicuously any precautionary warnings for the non-nutritive sweetener as may be prescribed by the Agency.

Warning for children.

15. The labels of all drug shall state prominently a warning statement to the following effect; "Keep this medicine out of reach of children".

Labelling of prescription DRUG.

16.—(1) In addition to compliance with the provisions in regulations 1 to 15 of these Regulations, the following shall apply—

(*a*) all prescription DRUG shall be properly labeled with the information on the package label as follows—

(*i*) the brand name, where applicable,

(*ii*) the generic or common name,

(*iii*) dosage form and strength,

(*iv*) listing of active ingredients,

(*v*) net content,

(*vi*) name and address of manufacturer and holder of Certificate of Registration,

(*vii*) batch or lot number,

(*viii*) manufacture and expiry dates,

(*ix*) storage conditions,

(*x*) warning for children, the statement in bold: "For external use only" for topical drug products or "For rectal or vaginal use only" or as appropriate, and

(*xi*) the statement "for veterinary use only" for veterinary only use and the withdrawal period shall also be stated ;

(*b*) the leaflet in all prescription DRUG shall provide the following information of the drug—

(*i*) the description of the drug as required in these Regulations,

(*ii*) clinical pharmacology,

(*iii*) indications and usage,

(*iv*) contra-indications,

(*v*) interactions,

(*vi*) warnings,

(*vii*) precautions,

(*viii*) adverse reactions,

(*ix*) drug abuse and dependence (where applicable),

(*x*) symptoms of overdose and treatment

(*xi*) dosage and administration,

(*xii*) the preparation for use,

(*xiii*) presentation,

(*xiv*) storage condition, and

(*xv*) any other information.

(2) Information regarding sub-regulation (1) (*b*) (*ii*) to (*ix*) of this regulation for a generic product shall be based on information approved for an innovator product and or national reference product as may be determined by the Agency.

(3) Prescription drugs shall not bear on its package label any statement, pictorial or representations of the indications of the drug.

Labelling of Over-The-Counter drug.

17.—(1) In addition to compliance with the provisions of regulations 1 to 15 of these Regulations, the following shall apply—

(*a*) the package label of over-the-counter DRUG shall be properly labeled and shall bear the following information—

(*i*) the brand name, where applicable,

(*ii*) the generic or common name,

(*iii*) quantitative list of all active ingredients,

(*iv*) indications for the drug,

(*v*) the net content of the drug in terms of weight, measure or numerical count,

(*vi*) the name and address of the manufacturer,

(*vii*) lot or batch number,

(*viii*) adequate directions for safe use of the drug,

(*ix*) dosage including amounts for use in specific age groups,

(*x*) route and frequency of administration,

(*xi*) warnings,

(*xii*) contra-indications,

(*xiii*) side effects,

(*xiv*) instruction for use,

(*xv*) a statement to the effect that a physician should be consulted if symptoms persists,

(*xvi*) the statement in bold : "For external use only" for topical drug products or "For rectal or vaginal use only" or as appropriate,

(*xvii*) a statement "For Veterinary use only" for veterinary use and the withdrawal period shall also be distinctly stated; and

(*b*) Information regarding sub-regulation (1) (*a*) (*v, viii - xiii*) above for a generic product shall be based on information approved for an innovator product national reference product as may be determined by the Agency.

(2) Where all the information required under these Regulations may not be contained on the labels of the over-the-counter drugs, they shall be accompanied by a leaflet insert.

(3) Where all the information required on the package of any over-the counter-medicine cannot be contained on the labels, such over-the counter-medicines shall carry package leaflets with complete label information in addition to the contra-indications and the labelling shall not contain any statement, which is false, misleading or exaggerated as to amount to a misinterpretation.

(4) Where the bottle, jar or other "immediate container" of the drug product has an outer wrapper or carton, such outer wrapper or carton shall bear all the information required to be specified on the label.

(5) Over-The-Counter Drugs shall not be labelled as treatment, preventive or cure for any of the diseases, disorders or abnormal states as identified in Schedule I of Food and Drug Act (Cap F32, LFN) 2004.

Drug in 5cm container.

18.—(1) Notwithstanding the provisions of these Regulations, a drug packed in a container that is 5cm or its equivalents or less, shall indicate the following—

(*a*) the brand name, where applicable ;

(*b*) the generic or common name ;

(*c*) lot or batch number ;

(*d*) net content ;

(*e*) manufacture and expiry dates ;

(*f*) manufacturer's name ; and

(*g*) registration number assigned to it in a manner prescribed by the Agency.

(2) For drug in blister packs packed in a container, each of the blister strips shall indicate the following—

(*a*) the brand name, where applicable ;

(*b*) the generic or common name ;

(*c*) the strength of the drug ;

(*d*) lot or batch number ; and

(*e*) expiry date.

(3) Any drug in a bulk package, except tablets, capsules or other dosage unit forms, intended for processing, repackaging or use in the manufacture of another drug shall be exempted from the labeling provisions of these Regulations, provided that, the label of the bulk drug contains the following information—

(*a*) the brand name (where applicable) ;

(*b*) the generic or common name ;

(*c*) net content ;

(*d*) lot or batch number ;

(*e*) manufacture and expiry dates ;

(*f*) name and location address of manufacturer, distributor or vendor ;

(*g*) storage conditions ; and

(*h*) the statement "Caution: For Bulk Drug Manufacturing Purposes Only".

Declaration of content of ingredients under composition.

19.—(1) List of all ingredients, active and inactive, shall be listed on product labeling and appear together without any intervening written, printed, or graphic matter.

(2) Full ingredient listing shall be provided on package label of Over-the -Counter drug products.

(3) Where label space cannot permit stating all ingredients, inactive ingredients may be designated with quantity sufficient ; (*qs*) on the package label and the full ingredient listing provided in the package insert.

(4) where the drug is in tablet or capsule form or other unit dosage forms, declaration of the quantity of an ingredient contained therein shall express the quantity of such ingredient in each such unit such as "Each film coated tablet contains……".

(5) Where the drug is not in a unit dosage form, any declaration of the quantity of an ingredient contained therein shall express the amount of such ingredient in a specified unit of weight or measure of the drug, or the percentage of such ingredient in such drug and such declaration shall be in terms that are informative to the end user.

(6) Statement of the percentage of an active ingredient in a drug product shall, where the—

(*a*) active ingredients and the drug product are both solids, means weight-in-weight :

(*b*) active ingredient is a liquid and the drug product is a solid; means percentage volume in weight ;

(*c*) active ingredient is a solid and the drug product is a liquid, percentage weight in volume ; and

(*d*) both the active ingredient and the drug product are liquids, means percentage volume in volume ;

(7) Where an ingredient is a derivative or preparation of a substance and the common or generic name of such ingredient does not indicate that it is a derivative or preparation of the parent substance, the labeling shall, in conjunction with the listing of the common or generic name of such ingredient, declare that such article is a derivative or preparation of such parent substance.

(8) For sterile DRUG, a quantitative list of preservatives present in it shall be indicated where applicable by their generic or common names.

(9) Certain specific warning or precautionary statement shall be included in the product labeling due to some inactive ingredients as may be determined by the Agency.

(10) Ingredient shall not be designated with compendia standard without truly being in compliance with such standard.

Expiry dating and batch or lot numbers.

20.—(1) Expiry date of a product shall—

(*a*) be determined by an appropriate stability testing described in the product registration submission and approved by the Agency based on the determined shelf life of the product ;

(*b*) be related to the storage conditions stated on the labelling, as determined by stability studies ;

(*c*) appear on the immediate container and the outer package, if any, unless it is easily legible through such outer package ; and

(*d*) bear the shortest shelf-life component of a co-packaged product.

(2) Batch or Lot number of—

(*a*) all product label shall indicate the batch or lot number in conjunction with the expiration dating ; and

(*b*) the label of a drug product shall be capable of yielding the complete manufacturing history of the drug product.

Score line information requirement for scored tablets.

21. To the extent as may be determined as appropriate by the Agency, a drug product formulated as a scored tablet shall state in the labelling, (package insert or package label), to the effect that—

(*a*) the break-line is functional and that tablet can be divided into equal halves to satisfy certain dosage requirement as indicated under dosage information ; or

(*b*) the break-line is not functional hence its presence is for ease of swallowing and not to divide into equal halves.

Offences and penalties.

22.—(1) Any person who contravenes any of 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 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 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.

23. 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.

24. The Agency is exclusively responsible for the enforcement of these Regulations.

Revocation.

25.—(1) The Drug Labelling Regulations 2005 is revoked.

(2) The revocation of these Regulations specified in sub regulation (1) of this regulation shall not affect anything done or purported to be done under the revoked Regulations.

Interpretation.

26. In these Regulations—

"*Active ingredient*" means any component that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or any function of the body of humans. The term includes those components that may undergo chemical change in the manufacture of the drug product and be present in the drug product in a modified form intended to furnish the specified activity or effect ;

"*Address*" means a place where the business of the manufacturer, sale, distribution, storage and display of drug and related products are carried out, which includes the house number, plot number, street name town or city, state and country ;

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

"*Batch*" means a defined quantity of material manufactured in one process, a series of processes or in a given part of a continuous process so that it may be expected to be homogeneous ;

"*Common name*" means with reference to a drug, the name in English Language by which the drug is commonly known ;

"*Co-packaged drug product*" means a *product* that contains two or more separate *DRUG* 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 substances of vegetable, animal or mineral origin or any preparation or admixture thereof manufactured, sold or advertised for use in—

(*i*) the diagnosis, treatment, mitigation, in man or animal,

(*ii*) restoring, correcting or modifying organic function in man and animal,

(*iii*) disinfections or the control of vermin, insects or pest, or

(*iv*) contraception ;

"*Expiry date*" means the date given on the individual container (usually on the label) of a product up to and including the Active Pharmaceutical Ingredient (API) and Finished Pharmaceutical Product (FPP) are expected to remain within specifications, if stored correctly and 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 name*" means the official non-proprietary name of a drug product or substance assigned by national or international bodies such as 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 ;

"*Identification mark*" means any single letter or combination of letters and numbers including words, company, mark, symbol, logo or monogram or a combination of letters, numbers and marks or symbols assigned by a drug firm to a specific drug product ;

"*Inactive ingredient*" means any component of a drug product other than an active ingredient ;

"*Ingredient*" means any substance in the drug, whether added to the formulation as a single substance or in admixture with other substances ;

"*Inner label*" means primary packaging material label ;

"*Label*" means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stenciled, marked, embossed or impressed on, or attached to a package or container of drug ;

"*Labelling*" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article";

"*Lot or Batch number*" means the number or a combination of numbers and letters specifically given to a drug which is linked to the manufacturing history of the drug;

"*National reference product or the comparator product*" means a pharmaceutical product with which a generic product is intended to be interchangeable in clinical practice;

"*Outer label*" means secondary packaging material label;

"*Over-The-Counter drug*" means any drug other than a prescription drug;

"*Package*" includes any suitable container in which any drug is wholly or partly placed or packed;

"*Package insert*" means an accompanying written or printed paper consisting of product information inserted in product pack or container;

"*Parenteral use*" means administration of a drug by means of hypodermic syringes, needles or other instrument through or into the skin or mucous membrane;

"*Prescription drug*" means a drug which can only be made available to a patient through a written prescription signed by a duly qualified and registered medical or dental practitioner or veterinary surgeon and dispensed by a registered and licensed pharmacist and such drug shall not be made available or sold to the general public without the said prescription;

"*Primary packaging material*" means packaging material that come in direct contact with the product such as bottle, blister, aluminum foils;

"*Principal display panel*" means the part of a package or label that is most likely to be displayed, presented, shown or examined under customary conditions of display for retail sale;

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

"*Proprietary or brand name*" refers to the exclusive name of a drug product owned by a company and registered under trademark law;

"*Secondary packaging material*" means packaging material in which primary packaging material is enclosed;

"*Scored tablets*" means tablet with a debossed line that runs across the planar surface of the tablet;

"*Tertiary packaging material*" means outer carton in which multiples of saleable units are packed such as shipper carton;

"*Therapeutic agent*" means a chemical substance that is used for the treatment or mitigation of a disease condition or ailment ; and

"*Withdrawal period*" means the period between the last dose of a drug and the time when the drug or its metabolite is depleted to acceptable Maximum Residue Limit (MRL) in the edible products (meat, milk or egg) of the animal.

Citation.

27. These Regulations shall be cited as the Drug and Related Product Labelling Regulations, 2021.

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

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