



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

**DRUG AND RELATED PRODUCT LABELLING
REGULATIONS 2019**

ARRANGEMENT OF SECTIONS

Commencement:

1. Scope
2. Prohibition.
3. No reference to National or International bodies
4. Labeling Information
5. Name and Address of manufacture, Certificate of Registration Holder, packer on label
6. Display of generic and brand name
7. Declaration of net content of drug
8. Brand name/Trade mark
9. Registration number assigned by the Agency
10. Identification mark
11. Labelling of dispensing measures
12. Package insert
13. Labelling of Parenteral preparations
14. Declaration of non-nutritive sweeteners
15. Warning for children
16. Labelling of Prescription drugs
17. Labelling of Over-the-Counter drugs
18. Drugs in 5cm container
19. Declaration of content of ingredients under composition
20. Expiry date and batch or lot numbers
21. Score line information requirement for scored tablets
22. Penalty
23. Forfeiture
24. Interpretation
25. Repeal
26. Citation

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

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

2. Prohibition

Except as provided in these Regulations, no person shall manufacture, import, export, distribute, advertise, display for sale or use any drug or drug product unless it is labelled in accordance with these Regulations.

3. No reference to national or international bodies.

No label of a drug or drug product shall make reference, directly or indirectly, to a National or international body, except as permitted/prescribed/specified by the Agency.

4. Labeling information

- (1) All information required to be indicated on the label shall be prominent, legible and distinct.
- (2) All statements must 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 written, 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 as 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 labelling requirements and drug safety information shall be clearly stated.

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

- (1) The label of a drug shall specify conspicuously the name and manufacturing location address of the manufacturer, and the name of the Certificate of Registration Holder.

- (2) Where a drug is manufactured under contract manufacturing arrangement, the name and manufacturing location address shall be indicated by a phrase that reveals the connection with the entity e.g. “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) – (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 location address of the manufacturer of a drug shall be complete on labels of all packaging components (i.e. Primary, Secondary and Tertiary), unless the immediate container of the drug contains 5 ml (or equivalents) or less of the drug product, in which case the address needs not be shown on the inner label.

6. Display of generic and brand name

- (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 (proprietary) name on all labeling components except in a running text of pack insert where generic (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) No product shall 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 info, 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 Regulation 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 (proprietary) 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 (proprietary) name.

7. Declaration of net content of drug

- (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 drugs in tablet, capsule, ampoule, vial or other unit dosage form shall be expressed in numerical count; the declaration of net content for drugs in other dosage forms shall be in terms of weight if the drug is solid, semi-solid, or viscous, or in liquid measure (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 thereof. A declaration of liquid measure (volume) of the contents shall be expressed in the liter and milliliter, cubic centimeter and subdivisions thereof.
- (4) A 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 (3tablets +2capsules) or 1 Combipack (1vial + 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 e.g. 2 x 1Co-pack.

8. Brand name/Trade mark

- (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 supercede and prevail.
- (3) The brand name of a drug product shall not be a sound or look alike to an 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 FPP and the brand name shall bear a differentiating suffix.

9. Registration number assigned by the Agency

- (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.

10. Identification mark

- (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 Regulation 10.1:
 - (a) drug products intended for use in a clinical trial investigation or bioequivalence studies;
 - (b) radiopharmaceutical drug products;
 - (c) drug products with product size, shape, physical characteristics which make imprinting technologically infeasible or impossible; and
 - (d) drugs administered solely in controlled healthcare settings.
- (3) Exemptions request shall be made in writing to the Agency.

11. Labeling of Dispensing measure

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

12. Package insert

All prescription only drugs 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.

13. Labelling of Parenteral preparations.

- (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 location 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 labelled, including the withdrawal period.

14. Declaration of non-nutritive sweeteners.

- (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 insert providing information concerning prescription drugs 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.

15. Warning for children.

The labels of all drugs shall state prominently a warning statement to the following effect: “Keep this medicine out of reach of children”.

16. Labelling of Prescription drugs

- (1) In addition to compliance with the provisions in Regulations 1 to 15 of these Regulations, the following shall apply:-
 - (a) all prescription drugs shall be properly labelled 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 location address of manufacturer and Certificate of Registration Holder,
 - (vii) batch or lot number,
 - (viii) manufacture and expiry dates,
 - (ix) storage conditions,
 - (x) warning for children,
 - (xi) the statement in bold: “For external use only” for topical drug products or “For rectal or vaginal use only” or as appropriate, and
 - (xii) the statement “ For veterinary use only” if for veterinary only use and the Withdrawal Period shall also be distinctly stated;
 - (b) the leaflet insert in all prescription drugs shall provide the following information on the drug:-
 - i) the description of the drug as required in these Regulations,
 - ii) clinical pharmacology,
 - iii) indications and usage,
 - iv) contraindications,
 - 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;

Information regarding 16 (1) (b)(ii-ix) above 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.

- (c) no prescription drugs shall bear on its package label any statement, pictorial or representations of the indications of the drug.

17. Labeling of Over-the-counter drugs

(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 drugs shall be properly labelled 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” if for veterinary use and the withdrawal period shall also be distinctly stated;
- (b) Information regarding 17 (1) (a) (v, viii - xiii) above 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.

- (2) where all the information required in these Regulations may not be contained on the labels of the over-the-counter drugs, they shall be accompanied by a leaflet insert; and
- (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) No person shall label over-the-counter drugs as treatment, preventive or cure for any of the diseases, disorders or abnormal states as identified in Schedule I of Food and Drugs Act Cap F32 of the Laws of the Federation of Nigeria 2004.

18. Drugs in 5 cm container.

- (1) Notwithstanding the provisions of these Regulations a drug packed in a container that is 5 cm (or 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,
 - (g) registration number assigned to it in a manner prescribed by the Agency.

(2) Blister packs.

Where a drug is packed in a container which meets the requirements specified in these Regulations, each blister strip 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) Bulk drugs.

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”.

19. Declaration of content of ingredients under composition

- (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) If 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 e.g. “Each film coated tablet contains.....”. If 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. Such declaration shall be in terms that are informative to the end user.
- (5) Statement of the percentage of an active ingredient in a drug product shall if 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; means percentage weight in volume
 - (d) both the active ingredient and the drug product are liquids, means percentage volume in volume.
- (6) If 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. e.g. Ciprofloxacin Hydrochloride E.q to Ciprofloxacin 500mg.
- (7) For sterile drugs, a quantitative list of preservatives present therein shall be indicated where applicable by their generic or common names.
- (8) Certain specific warning/precautionary statement shall be included in the product labeling due to some inactive ingredients as may be determined by the Agency.
- (9) No ingredient shall be designated with compendia standard without truly being in compliance with such standard.

20. Expiry dating and batch or lot numbers

(1) Expiry date

- (a) All products shall bear an expiration date determined by appropriate stability testing described in the product registration submission and approved by the Agency based on the determined shelf life of the product
- (b) Expiration dates shall be related to the storage conditions stated on the labeling, as determined by stability studies.
- (c) It shall appear on the immediate container and the outer package, if any, unless it is easily legible through such outer package
- (d) Expiration dating of a co-packaged product shall bear the expiration date of the component of the co-pack with the shortest shelf life.

(2) Batch/Lot number

- (a) All product label shall indicate the batch or lot number to appear in conjunction with the expiration dating
- (b) The batch or lot number on the label of a drug product shall be capable of yielding the complete manufacturing history of the drug product.

21. Score line information requirement for scored tablets

- (1) To the extent determined as appropriate by the Agency, a drug product formulated as a scored tablet shall state in the labeling (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.

22. 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.

23. 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.

24. Interpretation

In these Regulations, unless the context otherwise requires –

“**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;

“**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;

“**Council**” means the Governing Council of the Agency;

“**Co-packaged drug product**” means a 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 substances of vegetable, animal or mineral origin or any preparation or admixture thereof manufactured, sold or advertised for use in:

- (a) the diagnosis, treatment, mitigation, in man or animal;
- (b) restoring, correcting or modifying organic function in man and animal;

- (c) disinfections or the control of vermin, insects or pest; 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 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 e.g. 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”; “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 e.g. bottle, blister, aluminum foils, etc.;

“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;

“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 i.e. shipper carton;

“Therapeutic agent” means a chemical substance that is used for the treatment or mitigation of a disease condition or ailment;

“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.

25. Repeal of Drug Labelling Regulations 2005

- (1) The Drug Labelling Regulations 2005 is hereby repealed.
- (2) The repeal of these Regulations specified in Regulations 26(1) shall not affect anything done or purported to be done under the repealed Regulations

26. Citation

These Regulations may be cited as the Drug and Related Product Labelling Regulations 2019.

MADE at Abuja thisday of2019.

.....

Inuwa Abdulkadir Esq

Chairman Governing Council

National Agency for Food and Drug Administration and Control (NAFDAC)