

S. I. of 2005

**DRUGS AND RELATED PRODUCTS(REGISTRATION, ETC)
ACT 1999 (AS AMEMDED)**

Drug Labelling Regulations 2005

Commencement:

In the exercise of the power conferred on the Governing Council of the National Agency for Food and Drug Administration and Control (NAFDAC) by section 8 of the Drug and Related Products (Registration, etc) Act 1999 (as amended) and 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.

2. Prohibition

Except as provided in these Regulations, no person shall manufacture, import, export, distribute, advertise, display for sale or sell any drug that is not adequately labelled.

3. No reference to International bodies, etc.

No reference, direct or indirect to international bodies shall be made upon any label of a drug, except as is prescribed by the Agency.

4. Adequate and clear Labeling information

(1) All information required to be indicated on the label shall be prominent, legible and distinct.

(2) All information shall be in English Language, and may include other languages.

(3) Labelling shall be informative and accurate.

(4) Labelling shall not be false or misleading.

5. Name and Address of manufacturer, packer or distributor on label

(1) The label of a drug shall specify conspicuously the name and location address of the manufacturer, and where applicable the name and address of the packer or distributor.

(2) Where a drug is not manufactured by the person whose name appears on the label, the name and location address of the manufacturer shall be indicated by a phrase that reveals the connection with the person e.g. “Manufactured by.....for.....”, ‘Manufactured for.....by.....’, or any other wording that expresses the facts.

6. Display of proper name, brand name etc.

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

(2) The outer and inner labels of a drug shall show the generic name and strength thereof.

(3) Where a drug is branded, the generic and brand names shall be reflected on the outer and inner labels.

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

(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) Where a drug contains more than one active ingredient, all the common names shall appear on the principal display panel of the drug. However, if the drug is packaged in a container too small to bear this information, it may appear elsewhere on the label.

(7) The location address of the manufacturer of a drug shall be complete on the outer label, unless the immediate container of the drug contains 5 ml (or equivalents) or less of the drug product, in which case the address need not be shown on the inner label.

7. Declaration of net content of drug

(1) The outer label of a drug shall indicate :-

(a) the net content of the drug in the container in terms of unit weight, measure or number ; and

(b) for sterile drugs, a quantitative list of preservatives present therein shall be indicated where applicable by their generic or common names.

8. Trade mark

(a) where a drug product have a trade mark displayed on the label, the trade mark shall not give a wrong impression of the nature, quality or substance of the drug product;

(b) where the trademark registration is in conflict with any regulations or requirements of the Agency, the latter shall supercede.

9. Registration number assigned by the Agency

(1) The outer and inner labels of a drug shall show clearly the Agency registration number (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, the NAFDAC REG. NO. shall be shown on the tertiary and secondary packaging materials.

10. Identification mark tablets, capsules, etc.

(1) All tablets, capsules, caplets and similar dosage forms shall bear identification marks traceable to the manufacturer or holder of a certificate of registration of the drug product unless otherwise exempted by the Agency.

(2) The following classes of drug products are exempt 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 giving reasons why a waiver is justified.

11. Dispensing measure

All packages for oral paediatric liquid drug or drug products shall have included in them an appropriate measuring device graduated in 0.5ml to 10ml 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. Exemptions, etc

- (a) *Drugs in 5 cm container.*

Notwithstanding the provisions of these Regulations a drug packed in a container that is 5 cm (or equivalents) or less shall indicate the following:-

- (i) the brand name (where applicable),
- (ii) the generic or common name,
- (iii) lot or batch number,
- (iv) net content,
- (v) manufacture and expiry dates,
- (vi) manufacturer's name,
- (vii) registration number assigned to it in a manner prescribed by the Agency.

(b) *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:-

- (i) the brand name (where applicable),
- (ii) the generic or common name,
- (iii) the strength of the drug,
- (iv) lot or Batch number, and
- (v) expiry date.

(c) *Bulk drugs.*

A 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 exempt from the labeling provisions of these Regulations, provided that, the label of the bulk drug contains the following information:

- (i) the brand name (where applicable),
- (ii) the generic or common name,
- (iii) net content,
- (iv) lot or batch number,
- (v) manufacture and expiry dates,

- (vi) name and location address of manufacturer, distributor or vendor,
- (vii) storage conditions, and
- (viii) the statement “Caution: For Bulk Drug Manufacturing Purposes Only”.

14. Labelling of Parenteral preparations.

(1) The labelling of injectable drug products shall provide the health care practitioner and other users adequate information 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 accompanied by a leaflet 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 (IM, IV, etc.);
- (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 and irrigation shall bear the statement “ Not intended for intravenous injection”; and
- (k) injection for veterinary use shall be so labelled, including the withdrawal period.

15. Declaration of non-nutritive sweeteners.

(1) The outer and inner labels of all over-the-counter human drug 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 packaged insert providing information concerning prescription drugs for human use 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 .

16. 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”.

17. Prescription drugs labeling, etc.

In addition to compliance with the provisions in paragraphs 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,
 - (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 not intended for ingestion, or “For rectal or vaginal use only” etc. 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 regulation 16 of these Regulations,
 - (ii) clinical pharmacology,
 - (iii) indications and usage,
 - (iv) contraindications,
 - (v) Interactions,
 - (vi) warnings e.g. use in pregnancy, lactation etc.,
 - (vii) precautions,
 - (viii) adverse reactions,
 - (ix) drug abuse and dependence (where applicable),
 - (x) symptoms of overdose and antidote,
 - (xi) dosage and administration,
 - (xii) the preparation for use (shaking, dilution, etc.),
 - (xiii) presentation,
 - (xiv) storage condition, and
 - (xv) any other information;
- (c) no prescription drugs shall bear on its package label any statement, pictorial or representations of the indications of the drug .

18. Over-the-counter Drugs Labeling, etc.

(1) In addition to compliance with the provisions of regulations 1 to 15 of these Regulations, the following shall apply:-

- (a) the outer and inner labels 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 e.g. use in pregnancy, lactation etc.,
 - (xii) contra-indications,
 - (xiii) side effects,
 - (xiv) instruction for use (shaking, dilution, refrigeration etc.),
 - (xv) a statement to the effect that a physician should be consulted if symptoms persists for over the counter drugs that are self-limiting e.g. analgesics, cough remedies etc.,
 - (xvi) the statement in bold: “For external use only” for topical drug products not intended for ingestion, or “For rectal or vaginal use only” etc. as appropriate,
 - (xvii) a statement “For Veterinary use only” if for veterinary use and the withdrawal period shall also be distinctly stated;
- (b) where all the information required in this Regulation may not be contained on the labels of the over-the-counter drugs, they shall be accompanied by a leaflet insert; and
- (c) 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 150 of the Laws of the Federation of Nigeria 1990.

19. Penalty.

(1) A person who contravenes a provision of these Regulations is guilty of an offence and liable on conviction:-

- (a) in case of an individual, to imprisonment for a term not exceeding two years or to a fine not exceeding ₦50,000 or to both fine and imprisonment; and
- (b) in case of a body corporate, to a fine not exceeding ₦100,000.

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

- (a) every director, manager, secretary or other similar officer of the body corporate; or
- (b) every partner or officer of the firm; or
- (c) every trustee of the body concerned; or
- (d) every person concerned in the management of the affairs of the association; or
- (e) every person who was purporting to act in a capacity referred to in this regulation, are severally guilty of that offence and liable to be proceeded against and punished for that offence in the same manner as if they had themselves committed the offence unless they prove that the act or omission constituting the offence took place without their knowledge, consent or connivance.

20. Forfeiture.

In addition to the penalty specified in regulation 19 of these Regulations, a person convicted of an offence under these Regulations shall forfeit to the Agency the Drug Product and whatsoever is used in connection with the commission of the offence.

21. 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 and 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;

“drug” or “drug product” include 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 any date after which a drug is not recommended for use;

“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 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” includes any legend, word or mark attached to, included in, belonging to or accompanying any drug or package;

“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;

“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 components” include primary packaging material, secondary packaging material or tertiary packaging material;

“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 licenced pharmacist

