GUIDELINES FOR REGISTRATION OF NUTRITIONAL SUPPLEMENTS

FINAL DRAFT

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LIST OF ABBREVIATIONS

FAO	Food and Agriculture Organization
GMP	Good Manufacturing Practices
HACCP	Hazard Analysis Critical Control Point
ppm	Parts per million
RDA	Recommended Daily Allowance
RH	Relative Humidity
SADC	Southern African Development Community
SI	International System of Units
WHO	World Health Organization

INTRODUCTION

These guidelines are intended to provide guidance to competent authorities in SADC region to regulate the quality and safety of nutritional supplements. The nutritional supplements referred in these guidelines include vitamins, minerals, amino acids, enzymes, essential oils and natural substances of plant or animal origin.

It is emphasized that nutritional supplements are limited to products administered orally in the form of tablets, powder, capsules, gelcaps, softgels, granules and liquids. Products prepared in forms which require administration other than the oral route shall not be considered to be nutritional supplements and will be subject to other requirements. Nutritional supplements should be taken in quantities not exceeding recommended limits.

These guidelines have been divided into four chapters in which chapter one gives definitions of terms. Chapter two provides guidance to applicants on the general and administrative requirements. Product specific requirements and labelling are provided in chapters three and four respectively. An application form to be filled and submitted to competent authorities in SADC region is annexed to the guidelines.

CHAPTER I

DEFINITIONS

For the purposes of these guidelines, the following definitions shall apply:

1. Additive

Means a substance, other than a typical ingredient, which has been appropriately evaluated for safety and quality and is included in a nutritional supplement for a specific reason (e.g. to maintain stability of the finished product).

2. Batch

Means defined quantity of any nutritional supplement processed in a single process or series of processes such that it can reasonably be expected to be uniform in character and quality. Batch also means lot.

3. Certification of GMP or HACCP Compliance

Means a certificate or warranty accompanying an application for registration of nutritional supplements to be imported into a SADC region issued by competent authority certifying that the manufacturing premises comply with GMP or HACCP.

4. Codex

Means the Codex Alimentarius Commission responsible for execution of the joint FAO/WHO food standards programme for the purpose of protecting the health of food consumers and ensuring fair practices in the international food trade.

5. Competent Authority

Means an authority responsible for regulation of the quality and safety of nutritional supplements.

7. Composition

Means the ingredients including additives/excipients of which it consists, proportions, quality and purity in which those ingredients are contained.

8. Container

Means a bottle, jar, box, packet, sachet or other receptacle which contains or is to contain in it, and where any such receptacle is or is to be contained in another receptacle, includes the former but does not include the latter receptacle.

9. Country of origin

Means a country in which the nutritional supplement has been manufactured or produced;

10. Nutritional supplement

Means food supplement, dietary supplement, health supplement or nutraceutical product intended to supplement the diet, and shall include all of the following characteristics: -

(a) contains one or more of the following: vitamins; minerals; amino acids; essential oils; natural substances of plant or animal origin; enzymes; substances with nutritional or physiological function.

(b) is intended to be taken orally in the form of tablet, capsule, powder, softgel, gelcap, granules or liquid.

(c) is not represented for use as a conventional food or as a sole item of a meal or the diet.

(d) is labelled as such.

11. Ingredient

Means any substance used in the manufacture or preparation of nutritional supplement and present in the finished product in its original or in a modified form.

12. Label

Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on or attached to a packaging material of any nutritional supplement.

13. Manufacture

Means and includes all operations involved in the production preparation, processing, compounding, formulating, filling, refilling, transforming, packaging, re-packaging and labelling of nutritional supplement.

14. Manufacturer

Means a person or firm that is engaged in the manufacture or processing of nutritional supplements.

CHAPTER II

GENERAL REQUIREMENTS

2.1 Every person who intends to market nutritional supplements in SADC region must apply for registration of the product. When applying for registration to the relevant authority, the applicant is obliged to follow the instructions prescribed in these guidelines.

2.2 In order to avoid unnecessary delays, applicants are strongly urged to read these guidelines carefully to enable them prepare and submit acceptable applications. Submission of an application contrary to the requirements prescribed in this guide may result in delays, queries or rejection of the application.

2.3 Applicant

2.3.1 An application for registration of nutritional supplement shall either be made by the product owner, manufacturer or importer.

2.3.2 The applicant shall be accountable for the product and all information supplied in support of his application for registration of the product and alteration thereof.

2.3.3 Applicant shall monitor the quality and safety of the product marketed in the SADC region and inform the relevant authority in case of product defects and safety issues.

2.3.4 Applicant shall effect product recalls whenever necessary.

2.4 Application

2.4.1 A separate application is required for products containing different ingredients or manufactured at different sites or products containing the same nutritional composition but differing in forms.

The following shall be required to make a complete application:

a. Dully filled in application form (ANNEX 1).

b. Application form and the accompanied documents shall be filed in a spring A4 size file with collapsible edge made of biodegradable material.

c. Samples to be submitted together with an application for registration of nutritional supplements must be enough to enable evaluation and analysis of the product. Five samples of a commercial pack from one batch shall accompany the respective application.

2.5 Presentation of the application

2.5.1 The registration file shall be compiled in a well-presented and orderly manner. Pages of the file shall be sequentially numbered. Drawings, tables, diagrams, graphs etc. should also be well-annotated and numbered and appropriate references or cross-references clearly indicated.

2.5.2 All the prescribed information shall be submitted in English, French and Portuguese and all communication regarding the application shall be made in these languages. However, where original certificates are in another language, copies shall be presented together with certified translations.

2.6 Processing of application

2.6.1 When an application for registration is received, acknowledgement of receipt will be made and forwarded to the applicant.

2.6.2 Application shall only be accepted and processed if it is complete as stipulated under section 2.4. The relevant Authority may during evaluation of the product request for clarification or additional information or samples from the applicant. The processing of the

application shall be kept on hold until such clarification or additional information is provided.

2.6.3 Applications will be processed within defined timelines and applicants will be informed after the processing of their application has been completed. If the application is successful, the product will be registered.

2.7 Validity of registration

Subject to fulfilment of prescribed conditions, the registration of a product in SADC region shall be valid for three years unless sooner suspended, cancelled or revoked by the relevant authority.

2.8 Notification of change

2.8.1 If for any reason the registration holder changes any matter related to a registered nutritional supplement (e.g. change of composition, packaging, labelling etc) shall before marketing the changed product, notify the alteration along with justification and obtain an approval.

CHAPTER III

PRODUCT SPECIFIC REQUIREMENTS

3.1. Description

Provide brief description of the physical characteristics.

3.2. Intended use

Provide the use of the nutritional supplement and the target end user.

3.3. Benefits

Provide justification of the usefulness and benefits of the product to the intended target user.

3.4. Composition of the finished product

Provide full composition of the product including names of ingredient(s) and additives, standard reference and in the absence of the standard references, in-house standards, quantities per unit of measurement of each ingredient and reason of inclusion in a tabular form.

3.5. Specifications of raw material(s)

3.5.1. Submit comprehensive specifications of each ingredient used in the product.

3.5.2. Describe the limit or criteria of acceptance or rejection of raw materials.

3.5.3. Submit comprehensive specifications of permitted substances used including those added during the manufacture of the product but do not appear in the finished product.

3.6. Batch manufacturing process and in process quality control data

3.6.1 Give detailed description of the product manufacturing process supported by a well annotated manufacturing flow diagram.

3.6.1. Provide all in process quality and safety control tests performed on each batch, the stages at which tests are done, the frequency of sampling and number of samples taken each time a test is done.

3.7. Specifications of the finished product

3.7.1 Provide specifications of the finished product with adequate details of the test methods to enable independent quality control analysis to be conducted.

3.7.2 Provide certificates of analysis for at least three batches of the finished product.

3.8 Supplements containing herbal ingredient(s)

For nutritional supplements containing herbal ingredient(s) submit the following additional information: -

a. Summary of the profile of the plant used including botanical name, genus, species, subspecies, plant parts used, whether cultivated or wild, harvesting practices and treatment to obtain raw materials;
b. Data to demonstrate the safety of each herbal ingredient in human beings e.g. through bibliographic or scientific studies;
c. Description of the physiological functions of the herbal ingredient(s)/supplement to the intended user;

3.9 Contents of vitamins and minerals

3.9.1 The minimum level of each vitamin and/or mineral contained in a vitamin and mineral nutritional supplement per daily portion of consumption as suggested by the manufacturer should be 15% of the recommended daily intake as determined by FAO/WHO.

3.9.2 Maximum amounts of vitamins and minerals in vitamin and mineral nutritional supplements per daily portion of consumption as recommended by the manufacturer shall be set, taking the following criteria into account:

2.8.2 Upper safe levels of vitamins and minerals established by scientific risk assessment based on generally accepted scientific data, taking into consideration, as appropriate, the varying degrees of sensitivity of different consumer groups;

2.8.3 The daily intake of vitamins and minerals from other dietary sources.

3.10 PACKAGING

The product shall be packed in containers which will safeguard the hygienic and other qualities of the food. The containers, including packaging material, shall be made only of substances which are safe and suitable for their intended use.

3.11 Shelf life and storage conditions

3.11.1 Submit stability studies report for at least three batches of the finished product which shall include the study design (protocol), including test conditions (humidity and temperature), type of container, results and conclusions. Testing must be conducted using containers and closures intended for marketing of product. The test condition must mimic SADC climatic conditions of

30±2°C/65±5%RH for real-time and 40±2°C/75±5%RH for accelerated stability data. Data for accelerated stability testing must be at least for six months.

3.11.2 Attributes (parameters) to be tested should be those susceptible to change and are likely to influence the quality and safety of the finished product and they shall at least cover appearance for all product forms, levels of nutrients, physicochemical properties such as pH, dissolution, disintegration and microbial limits.

CHAPTER IV

REQUIREMENTS FOR LABELLING OF NUTRITIONAL SUPPLEMENTS

For the purposes of these guidelines the following are the general labelling requirements: -

4.1. Nutritional supplements shall not be described or presented on any label or in any labelling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any respect.

4.2. Nutritional supplement shall be labelled in such a way that: -

4.2.1 It does not in any way either directly or indirectly purport to prevent, diagnose, treat, cure or mitigate any disease;

4.2.2 Imply that nutritional supplements can be used for the replacement of meals or varied diet;

4.3. The label of the nutritional supplement shall contain a cautionary statement where applicable e.g. adverse effects or risks of excessive intake, contraindications, any warning and precautions associated with the use of the product and instruction that the product should be stored out of reach of children.

4.4. **Every container of any nutritional supplement shall be affixed with a label bearing the following information in clearly legible and indelible letters in SADC official languages i.e. English, French or Portuguese: -**

4.4.1.Product name

4.4.1.1. Brand or trade name of the product.

4.4.1.2. Identify the product as “food or dietary supplement” or describe the type of supplement i.e. **supplement** preceded by the name of the dietary ingredient(s) e.g. calcium supplement, multivitamin supplement, etc.

4.4.2.List of ingredients

4.4.2.1 Except for single ingredient nutritional supplements, a list of ingredients shall be declared on the label with the corresponding quantities per specified unit of measure.

4.4.2.2 All ingredients shall be listed in descending order by weight (m/m) at time of manufacture of nutritional supplement.

4.4.2.3 If the ingredient is from animal or plant, scientific name of the plant and part of animal or plant used shall be declared.

4.4.2.4 Labelling must include the quantity per intake for each ingredient, the form and source e.g. "calcium in form of calcium carbonate from oyster shell.

4.4.2.5 Additives/excipients such as fillers, artificial colours, sweeteners, flavours, or binders shall be listed by their specific names/E-numbers and qualified by words “natural” or “artificial” in descending order in weight or volume e.g. E110/Sunset yellow as artificial colorant.

4.4.3. Nutritional information

Label must declare in numerical form the amount of nutrients present in the product per portion of the product as recommended for daily consumption or amount per unit for single use;

4.4.4. Net content and weight

The net contents shall be declared in the metric system (Sl units) by weight for solid or powdered products, volume for liquid or number for tablets and capsules.

4.4.5. Particulars of Manufacturer

Name and address of the manufacturer including country of origin of the nutritional supplement shall be declared.

4.4.6. Batch/Lot identification

Each product shall be permanently marked in code or in clear expression to identify the producing factory and the batch/lot number.

4.4.7. Manufacturing, expiry date and storage instructions

4.4.7.1. All product labels shall be permanently marked with date of manufacture and expiry, which shall indicate at least the month and year.

4.4.8 Appropriate storage conditions recommended for the product shall be declared.

4.4.9 Instruction for Use

Clear and concise instruction for use (quantity, frequency, age group, special conditions, etc) and amounts to be taken daily shall be included on the label to ensure correct utilization of the product.

4.4.10 Precautions

State any precautions to be observed when using the nutritional supplement.

4.4.11 Additional information

Any additional information for effective use of the product may be included as package insert.

ANNEX I

ZAMBIA MEDICINES REGULATORY AUTHORITY

APPLICATION FORM FOR MARKETING AUTHORIZATION/MARKETING AUTHORIZATION RENEWAL OF NUTRITIONAL SUPPLEMENTS

1.0 Particulars of product:

1.1 Brand Name: ……

1.2 Common name……

1.3 Brief description of the physical characteristics of the product

……

……

1.4 Brief description of the use of the product and intended end user (use a continuation page if necessary)……

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1.5 Type of materials for the packaging container and liner if any

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……

1.6 Type of materials for cap/crown/closure and liner if any
……
……
1.7 Type of seal
……
1.8 Retail packaging unit(s)
……
1.9 Shelf life
……
1.10 Shelf life after opening of container……
1.11 Shelf life after reconstitution (where applicable)……
1.12 Recommended storage conditions……

2.0 Particulars of applicant

2.1Name……
2.2 Physical address (plot/block No./street/Village/district/region……
……
……
2.3 Postal Address……
2.4
Telephone……
2.5
Fax……
2.6 E-Mail……

2.7 Local manufacturer, processor or importer ……

3.0 Particulars of manufacturer

3.1Name

……

3.2Physical

Address……

3.3Postal

Address……

3.4Phone……

.

3.5 Fax……

3.6 Email……

4.0 In case of imported nutritional supplements provide the following:

4.1 Authoritative document from competent authority of the country of origin indicating that the product is authorized for sale as nutritional supplement in that country.

4.2 Documentary evidence indicating that the product has been approved for use in any other countries (if any).

4.3 Document from relevant recognized organization indicating that the manufacturing facility complies with GMP, HACCP or other quality assurance programme.

5.0 Ingredients used

List ingredients in descending order of proportion or weight using common names and SI units.

5.1 Typical nutritional ingredients

S/N	**Name**	**Proportion (e.g. %, ppm,**	**Purpose of use**

		units)	

5.2 Additives

S/N	**Name (Specific, common, chemical, technical) or E-number**	**Levels**	**Purpose of use**

9.0 Declaration by an applicant

I,

……

the ……(position in the company) and a dully authorised representative of ……

do hereby declare and certify that all the information filled in this form and all the accompanying documents are true and correct and confirm that the information referred to in this application is available for verification.

Signature……

Date……………………………………………………………….

Official Stamp/Seal……………………………………………………