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Review Article

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Comparisons of registration requirements of Nutraceuticals in Philippines, Tanzania, Cambodia and India

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Abstract

"Nutraceuticals" are the combination of Nutrition and pharmaceutical. The term Nutraceutical was given by Dr. Stephen in 1989. A dietary supplement is a product taken by mouth that contains a dietary ingredient (Vitamins, Minerals, Herbs, Amino acids etc.) Numerous definitions and nomenclature for dietary supplements exist worldwide. In India Food Safety and Standards authority (FSSA), defines Nutraceuticals as "foods for special dietary uses or functional foods or health supplements". In Philippines Nutraceuticals are known as food supplement & dilatory supplement. In Sudan, Nutraceuticals are known as dietary supplement & health product .In Cambodia Nutraceuticals are known as health supplement product. Every country has their own guidelines, regulatory requirements which deal with regulatory registration procedures of Nutraceuticals. In order to enter the Indian Nutraceutical market, some of the very important areas of focus include product evaluation, actual product analysis, procuring licenses and developing India specific health and label claims.

Keywords: Nutraceuticals, Registration procedure of Nutraceuticals, Food Safety and Standards authority (FSSA)

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1. Introduction

The term Nutraceuticals was first introduced by D.r Stephen DeFelice in 1989 and in 1994 DeFelice defined Nutraceuticals as "Any substance that may be considered a food or part of a food and provides medical or health benefits, including the prevention and treatment of disease". It includes vitamins, minerals, herbs and other botanical amino acid, dietary substances, essential oils, natural substance of plant and animal origin as a supplementary diet for human use. These nutritional supplements are limited to the products which are to be administered orally in the form of tablet, capsule, granules, and powder, liquid or soft gel. (1)

Nutraceutical are associated with the treatment or prevention of many diseases as following and they provide treatments in terms of:

- Anti-diabetic
- Anti-cancer
- Chronic heart disease
- Anti-hypertensive
- Hypertension
- Arthritis

Numerous definitions and nomenclature for dietary supplements exist worldwide. In India Food Safety and Standards authority (FSSA), defines Nutraceuticals as "foods for special dietary uses or functional foods or health supplements". In Philippines Nutraceuticals are known as food supplement & dilatory supplement. In Sudan, Nutraceuticals are known as dietary supplement & health product. In Cambodia Nutraceuticals are known as health supplement product. (2)

2. Discussion about Nutraceuticals

2.1 Regulation of Nutraceuticals in India

In Indian market Nutraceutical is a new word. Nutraceuticals has a spectacular annual growth rate. There is 25 % annual growth of Nutraceuticals in India which is same as Japan. According to Indian definition of Nutraceuticals it must have the listed ingredients and also must have the general given properties. Nutraceuticals do not include traditional foods.

Nutraceuticals which contain some important component having therapeutic activity or formulated to satisfy particular dietary requirement. These are notified in such a way that all the required ingredients in the food stuffs must differ from the rules of Indian standards presented as such, from the ordinary food stuffs if though there exist any kind of food stuff then it must contain one or more than one of the following composition or ingredients. This has been defined in the following such as: These include the parts which are obtained in type of liquid extract, dry powder, or extract in the way of ethyl alcohol and hydro alcoholic thee may in the form of combination or singly added from the plants and namely botanicals. Vitamins, minerals, proteins and amino acid or their components of metals should not exceed more than the limits which has been mentioned in the recommended daily allowance (RDA) for the Indian rules and regulation. (3)

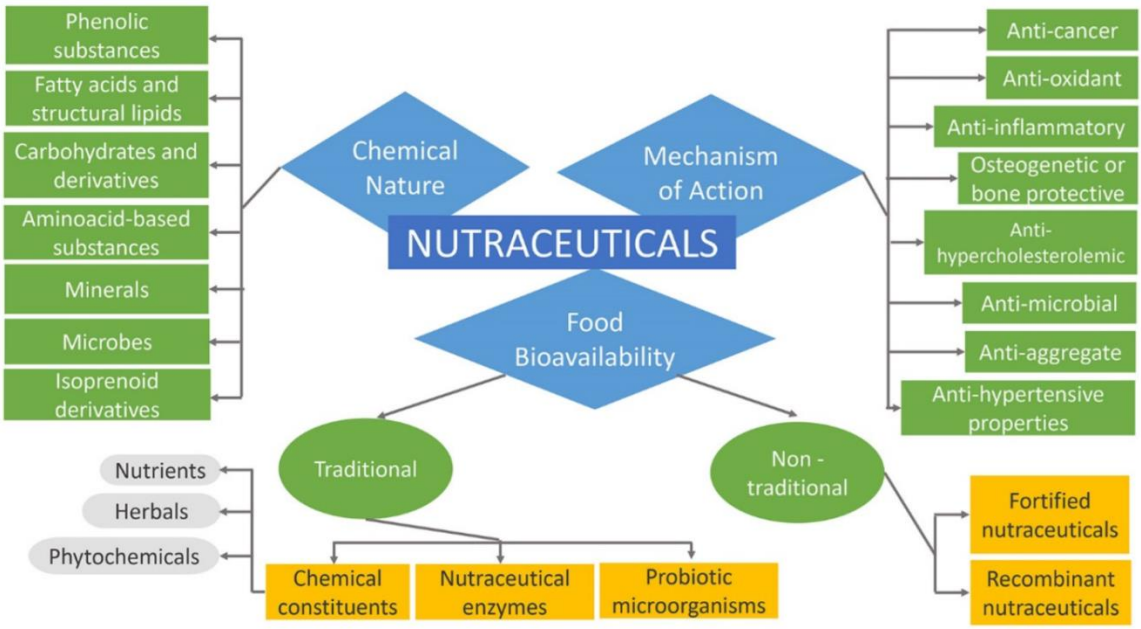

Figure 1. Functional Classification of Nutraceuticals (4)

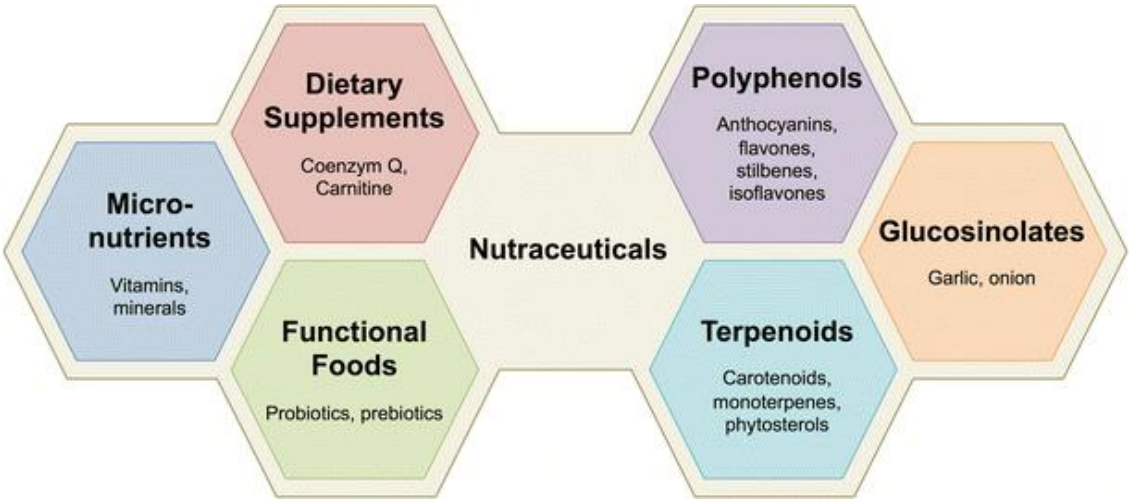

Figure 2. Type of Nutraceuticals (5)

Checklist of registration requirements:

a) Form-B Duly completed and signed

b) Layout of the manufacturing unit or it can also be in the form of blueprint.

c) Directors name and their list

d) Equipments and Machinery used in the manufacture's list with their names

e) Photo I.D and with the proof of address

f) The products which has to be manufactured are listed

g) Authority letter

h) Report of analysis

i) Premises owning proof.

j) Affidavit of Proprietorship

k) Copy of certificate obtained under Coop Act – 1861

l) NOC & Copy of License from manufacturer

m) Food Safety Management System plan or certificate (if any)

n) Source of milk or procurement plan for milk including location of milk collection centres etc. in case of Milk and Milk Products processing

o) Source of raw material

p) Pesticide residue report of water

q) Recall plan

r) Form IX

s) Certificate provided by ministry of tourism

t) For transporters-supporting documentary proof

u) Declaration form

2.2. Philippines:

Regulatory Authority: - Food and Drug Administration (FDA), Philippines

Dossier Format: - ACTD

The Nutraceuticals market of Philippines is presently in its early growth stage due to the dependence on traditional pharmaceutical medicine system by growing middle class population. Philippines Nutraceuticals market basically can be divided into 3 major categories:

- Vitamins and Dietary supplements
- Functional Beverages
- Functional Foods

Checklist of registration requirements for food supplements:

a) Letter of Application

b) Copy of Valid LTO of Food Manufacturer/Distributor/Importer

c) Unit Dose and Batch Formulation

d) Technical Specifications of the Finished Product

e) Analytical Test Methods Used for Testing the Finished Product

f) Representative Sample of the Product

g) Labeling Materials

h) Stability Studies to Support Claimed Shelf-Life

i) Master Manufacturing Procedures

j) Certificate of Analysis of the Finished Product

k) Technical Specifications of the Ingredients (6)

2.3. Tanzania

The Tanzania Food and Drugs Authority (TFDA) was established under the Tanzania Food, Drugs and Cosmetics Act 2011, Cap 219 with the mission of protecting and promoting public health by ensuring quality, safety and effectiveness of food, medicines, cosmetics and medical devices. One of the TFDA functions is to conduct pre-marketing evaluation of the regulated products to ensure that they meet standards of quality, safety and effectiveness before they are registered i.e. being officially allowed into the market.

In trying to streamline and effectively control food supplement products these guidelines have been developed by TFDA to outline requirements for registration of products in Tanzania.

Food supplement or nutritional supplement or dietary supplement or Nutraceutical

Means a product other than tobacco intended to supplement the diet, and shall include all of the following characteristics:

A. Contains concentrated source of 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 or contains any combination of any of these.

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 food supplement

General Requirements

• Applications shall be done by submitting a dully filled in application form A accompanied with information as prescribed in these guidelines. All documents shall be in Kiswahili or English languages

Applicant

An application for registration of food supplement shall either be made by the owner, manufacturer, processor or importer. 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. Applicant shall monitor the product in the SADC market and inform the TFDA. Immediately after the detection of any problem relating to the registered product such as serious manufacturing defects which may endanger public health, Applicant shall affect product recalls whenever necessary.

Application

A Separate Application is required for each product, I.E. Products containing different ingredients or manufactured at different manufacturing 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

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 food 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 submitted to a national medicines/food regulatory authority.

d. Payment of prescribed fees as stipulated by the national medicines/food regulatory authority

Presentation of the Application

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.

All The Prescribed Information Shall Be Submitted In English And All Communication Regarding The Application Shall Be Made In English. However, Where Original Certificates Are in another Language, Copies Shall Be Presented Together with Certified English Translation

Submission

One hard and one electronic copy of an application file will be submitted to the respective national medicines/food regulatory authority of Tanzania

Processing of Application

When an application for registration is received, acknowledgement of receipt will be made and forwarded to the applicant. Application shall only be accepted and processed if it is complete as stipulated under Section presentation of the application the 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 information is provided. The processing of an application takes about 240 working days excluding the period when the application is kept on hold pending clarification or submission of additional information. Applicants will be informed after the processing of their application has been completed. If the application is successful, the product will be registered.

Validity of registration

Subject to payment of annual retention fees, the registration of a product shall be valid for three years unless sooner suspended, cancelled or revoked by the Authority.

Renewal of registration

All applications for renewal of registration shall be made on an application for renewal form (A) at least 60 days before expiry of the existing registration. All applications for renewal of registration shall be made as prescribed under these guidelines. (7)

2.4. Cambodia

Health Supplement is the product which has been derived from plants, animals, with a physiological effect alone or in combination with vita mins, protein, enzymes, extract from organ, minerals. The health supplement can also be marketed in various forms, such as tablets, capsules, soft capsules, pastilles, ampoules of liquid, powder, drops dispensing bottle and other forms designated to be taken in measured small unit quantities.

Health supplement means products and the purpose of which are:

a) To improve and maintain a healthy condition,

b) To supplement the normal diet

c) For the use of patient under dietary regimes, such as obesity, diabetic patients, hypertension, dieting, etc.

Checklist of registration requirements (8,9)**:**

1) Administrative Document

Application form

- Free Sale certificate (Letter Head of Drug Regulatory Authority: DRA)
- GMP or ISO Certificate
- Hygienic certificate
- Product Information

Table 1. Comparison between Emerging market (10)

	Philippines	Tanzania	Cambodia	India
Parameters				
Regulations				
Definitions	Philippines Nutraceuticals are known as food supplement & dilatory supplement under the Food and Drug Administration (FDA) Philippines regulations.	TFDA define Nutraceutical as "food supplement product".	Cambodia Nutraceuticals are known as health supplement product under the Department of Drugs and Food (DDF) in Cambodian regulations.	Food Safety and standards authority (FSSA) defines Nutraceuticals as "Food for special uses '' in India

	Philippines	Tanzania	Cambodia	India
Responsible regulatory authorities for registration of Nutraceuticals	Food and Drug Administration (FDA),Philippines	Tanzania food and drug authority regulation (TFDA)	Department of Drugs and Food (DDF)	Food Safety and Standards Authority of India
Registration came into force in year	2009	2003	NA	2011
Dossier Format	ACTD	CTD	ACTD	CTD
Dossier Language	English	English	English	English
Regulatory requirements for registration	Letter of Application GMP Certificate Free Sale Certificate Stability Studies CoA COPP Sample	a) Product licensing b) Refusal or revocation of registration c) Labeling d) Site licensing e) GMP f) Adverse reaction reporting	Application Form Free Sale Certificate GMP Certificate Hygienic certificate CoA Stability study	Product Approval License / import license
Rules and regulation for licensing and registration	Food and drug administration of Philippines Rule	Tanzania food and drug authority regulation	Department of Drugs and Food (DDF)	The food safety and standard regulation
Registration requirement				
Fees for registration	Php. 250	Tshs. 500	NA	Rs. 100
Validity of registration	2 to 5 year	3 year	3 Year	1 to 5 year
Processing of application	180 Days	240 days	NA	60 Days
Authorities for approval of claim	FDA Philippines	Tanzania	DDF Cambodia	FSSA
Required health warning	NO	No	YES	YES
Health claim	-Nutrition claim -Health claim	- Specific health claim - General health claim	NA	ingredients (nutrient or nutritional) - function claims enhanced - health maintenance claims - anti-ageing claims
Labeling Requirements (9)				
Product name	√	√	√	√
Composition	√	√	√	√
Dosage Form	√	√	√	√
Administration & Dose	√	√	√	√
Packaged Size	√	√	√	√
Manufacture name & Address	√	√	√	√
Distributer Name & Address	√	×	×	√
Batch No.	√	√	√	√
Expiry Date	√	√	√	
Side Effect	√	√	√	√
Contraindication	√	√	√	√
Precaution	√	√	√	√

	Philippines	Tanzania	Cambodia	India
Storage condition	√	√	√	√
Registration No.	×	√	×	×
License No.	×	×	×	√
Packaging requirement (10)				
Presentation requirement	The Language Shall Be Either In English Or Filipino Or A Combination	Label must be in English or Kiswahili or both	English	English

2) Technical Documents

- Unit Formula and Batch Formula
- Manufacturing Process –in process control
- Control Procedure of Raw Materials
    - -Active ingredient(s) and Inactive ingredients.
    - -Certificate of analysis of active ingredients with its specifications
- Control Procedure of the finished product
    - -Certificate of analysis of the finished product with its specifications.
- Storage condition of the finished product and its predicted expiry date.
- Stability study

3. Conclusion

The Nutraceutical is an emerging business in the world of Pharmaceuticals and the growth of the business in the forth coming years are huge. In India, Food Safety and Standard Authority of India [FSSAI] is the only single authority to regulate production, distribution, and marketing of Nutraceutical in India. Globalization of the Nutraceutical and functional food industries present significant challenges to stakeholders, not the least of which is the regulatory variance between countries active in the marketplace. Hence, when any new participant wants to enter the Indian Nutraceutical market, it is very important to comply with the regulatory framework, so that the business will run smoothly. We have seen India and Tanzania, Cambodia and Philippines registration of regulatory frameworks that are current and in force at the moment of this review. India mainly all manufacture shall follow the guideline criteria well explained and describe there all submission process their specification and main benefit is that only approved product get license and have authority to marketing their product from dissertation work we have make clear to the comparative study of Nutraceutical product in different countries registration process, labeling regulation for Nutraceutical in India, and Tanzania, Cambodia and Philippines.

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Conflict of Interest

The authors declare that there is no conflict of interest regarding the publication of this article

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