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Review Article

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Comparison of Dietary Supplements Product Registration requirements in Singapore, Malaysia, Ghana, Zimbabwe and India

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Abstract

Nowadays, diet is thought to be much richer than it used to be. The people's ignorance of the basic principles of nutrition has led a large part of the population to a non-balanced diet that is high in both calories and fat and low in proteins, vitamins and minerals. This is where Dietary supplement comes in role as it is any vitamin, mineral, herbal product, or other ingestible preparation that is added to the diet to benefit health. Dietary supplements are used worldwide and represent a broad category of ingestible products that are distinguishable from conventional foods and drugs. They do not belong to the category of common food neither medicines nor special dietary products and not intended for specific categories of people. It is very important to ensure that any product entering the market completely complies with the regulatory guidelines and requirements. The regulation of dietary supplement in the five countries India, Singapore, Malaysia, Ghana and Zimbabwe is reviewed and compared.

Keywords: Dietary Supplement, Nutrition, Regulations

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1. Introduction

A dietary supplement is a manufactured product intended to supplement one's diet by taking a pill, capsule, tablet, powder or liquid. A supplement can provide nutrients either extracted from food sources or that are synthetic in order to increase the quantity of their consumption.

The global dietary supplements market size was valued at USD 151.9 billion in 2021 and is expected to expand at a compound annual growth rate (CAGR) of 8.9% from 2022 to 2030.

Dietary supplements are playing an important role in the development of future therapeutics but it depends on the control of purity, efficacy and safety. So, when a product enters the nutraceutical market it is necessary to ensure that it meets the safety standards according to regulation of different countries. Here, the regulations of five countries (India, Singapore, Malaysia, Ghana and Zimbabwe) are reviewed and compared.

2. India

A dietary supplement may be defined as a product taken by mouth that contains a dietary ingredient and / or a new dietary ingredient intended to supplement the diet. (1)

Following documents are required for the approval of dietary supplement (2):

- Form A
- Declaration form which has to be self-attested
- Manufacturing/ import license
- Form B and form C
- Declaration form which has to be self-attested
- The copies of documents listed below

Documents to be enclosed with the new application for license/ import license to State/ Central Licensing Authority (2):

- Form-A
- Form B
- Blueprint/layout plan of the processing unit
- List of Directors
- Name and List Machineries to be used in

the process
- Photo I.D and address proof
- List of food category desired to be manufactured.
- Authority letter with name and address of responsible person
- Analysis report
- Proof of possession of premises
- Partnership deed/Affidavit/Memorandum & Articles
- NOC from manufacturer
- Food safety management system plan or certificate
- Source materials
- Pesticide residues report of water
- Recall plan
- NOCs

3. Singapore

A health supplement is a product that is used to supplement a diet and to support or maintain, enhance and improve the healthy functions of the human body. It cannot be an injectable or a preparation that needs be sterile, such as injections and eyedrops. It cannot be an item of a meal or diet.

Food and supplements of food nature come under the concern of the Singapore Food Agency (SFA). Health supplements are not subject to approvals and licensing by HSA for their importation, manufacture and sales. HSA prohibits the addition of medicinal ingredients such as steroids in health supplements. HSA also sets strict limits on toxic heavy metals in these products. Dealers have the obligation to ensure that their products are not harmful or unsafe, and that they conform to the following guidelines before supplying health supplements into Singapore.

Documents required for filling the dossier of the health supplement:

- Copy of GMP Certificate
- Certificate of Free Sales (CFS)
- Batch Manufacturing Formula
- Description of Manufacturing Process and Process Control
- Raw Material COA
- Finished Product Specification
- Analytical Procedure for Finished Product
- Finished Product COA
- Stability Protocol and Stability Data
- Documents to substantiate claims
- Outer and inner artwork proposed for Singapore
- Package Leaflet proposed for Singapore. (3)

4. Malaysia

A Health Supplement (HS) means any product that is used to supplement a diet and to maintain, enhance and improve the health function of human body. It is presented in small unit dosage forms (to be administered) such as capsules, tablets, powder, liquids and shall not include any sterile preparations (i.e. injectable, eyedrops).

Documents required for registration are:

- BMR
- Finished product specification and COA
- Stability Data Reports
- Letter of authorization of product owner
- Letter of appointment of contract manufacturer and/ or re-packer
- Letter of acceptance as contract manufacturer and/ or re-packer
- Certificate of Pharmaceutical Product (CPP), Free Sale Certificate (CFS) and Good Manufacturing Practice (GMP)
- Attachment of Protocol Analysis
- Finished Product Quality Control (FPQC)

5. Ghana

"Food/Dietary or Nutritional Supplement" means - concentrated sources of nutrients or other substances produced in a pharmaceutical dosage form such as tablets, gelatine capsules (soft or hard), sachets, syrups and powders. Dietary components include herbs, vitamins and minerals (with concentration less than the recommended daily allowance), natural oils, royal jelly, pollen and bee propolis. All these ingredients can be included in dietary supplements on the condition that their sole function is supplementation and improvement of body function. (4,5)

Documents required for registration are:

- Covering Letter
- Signed Declaration
- Fully Completed Application (Appendix I-IV)
- Certificate of Analysis (Finished Product)
- Free Sale Certificate (Foreign Product)
- Stability Study Reports
- Samples (As per FDA sample schedule)
- 4 Copies of Label & Packaging Material
- 4 Copies of Package Insert (5)

6. Zimbabwe

Complementary medicines means any substance or mixture of substances which is used, or is manufactured, sold or represented as suitable for use, in:

a) he mitigation or prevention of disease or abnormal physical mental state or the symptoms thereof in human beings or in animals;

b) restoring, correcting or modifying any physical, mental or organic function in man or in animals; which originates from a plant, mineral, animal or insect and includes substances generally referred to as Aromatherapeutic Substances, Ayurvedic Medicines, Energy Substances or Medicines, Homeopathic Remedies, Nutritional Substances in Pharmaceutical Form, Traditional Chinese Medicines, Traditional Dutch Remedies, Unani Tibb Medicines, Western Herbal Medicines, and such other

medicines or remedies as may be approved by the Authority (6);

Documents required for registration are:

- Cover letter
- A completed and signed C.M.1
- Declaration by the applicant
- Proof of payment of appropriate fees
- Product Samples

Table 1. Comparative summary of Regulatory requirements for Health Supplement

Sr. No.	Parameter	India	Singapore	Malaysia	Ghana	Zimbabwe
			Regulations			
1	Definition	A dietary supplement may be defined as a product taken by mouth that contains a dietary ingredient and / or a new dietary ingredient intended to supplement the diet.	A health supplement is a product that is used to supplement a diet and to support or maintain, enhance and improve the healthy functions of the human body.	A Health Supplement (HS) means any product that is used to supplement a diet and to maintain, enhance and improve the health function of human body.	"Food/Dietary or Nutritional Supplement" means concentrated sources of nutrient or other substances produce-d in a pharmaceutical dosage form such as tablets, gelatine capsule (soft or hard), sachets, syrups and powder	Complementary medicine means any substance or mixture of substances which is used, or manufactured, sold or represented as suitable for use.
2	Rules and regulation for licensing and registration	The food safety and standard regulation	Sale of Food Act and the Food Regulations	Under Drug Control Regulatory by The Control of Drugs and Cosmetics *Regulations* 7(1)(a)	Food and Drug Authority Guidelines	Medicines and Allied Substances Control (Complementary Medicines) Regulations
3	Registration came into force in year	2011	2019	1992	2013	2015
4	Responsible regulatory authorities for registration of Dietary supplement	Food safety and standard authority of India (FSSAI)	Health Sciences Authority	National Pharmaceutical Regulatory agency (NPRA)	Food and Drugs Authority Ghana	Medicines Control Authority of Zimbabwe (MCAZ)
5	Regulatory Agency Website	https://fssai.gov.in	www.hsa.gov.sg	www.npra.gov.my	https://fdaghana.gov.gh	www.mcaz.co.zw
6	Regulatory requirements for registration	- Product Approval - License / import license	- Product safety and quality standards - Labelling standards - Health supplement Claims	- Product Approval - Health supplement claims	- Safety reports - COA - Free sale certificate - Stability study report - Samples	- Cover letter - A completed and signed C.M.1 - Declaration by the applicant - Proof of payment of appropriate fees - Manufacturing and marketing authorization(s)/international registration status - Product Samples

Registration requirement						
7	Fees for registration	Rs. 100	None	None	120 GH¢	None
8	Validity of registration	1 to 5 years	NA	5 years	3 years	1 year
9	Approval of application	60 days without queries 90 days with queries	NA	Single active ingredient: 116 days Two or more active ingredients: 136 days Disease risk reduction claims (high claims): 245 days	1-2 months	1 or 2 review cycles
10	Authorities for approval of claim	Food safety and standard authority of India (FSSAI)	Health Sciences Authority	National Pharmaceutical Regulatory agency (NPRA)	Food and Drugs Authority Ghana	Medicines Control Authority of Zimbabwe (MCAZ)
11	Required health warning	Yes	Yes	Yes	Yes	Yes
12	Health claim	- Ingredients/ Nutrition Claims - Function claims - Health maintenance claims - Anti-ageing claims	- General health claims - Specific health claims	- General or nutritional claims - Functional claims - Disease risk reduction claims	None	None
Labelling Information						
13	Ingredients And Contents	- List of ingredients and additives used in the food listed in descending order of the proportions - Declaration of foods as veg/ non- veg/ vegan - Declaration of net content in package	- List of ingredients and additives used in the food listed in descending order of the proportions - Declaration of foods and ingredients known to cause hypersensitivity - Declaration of net content in package	- Ingredients shall be indicated in descending order of proportion by weight - Allergens in food product to be declared - Quantity of food in package is to be declared	- All ingredients shall be listed in descending order of ingoing weight (m/m) at the time of the manufacture of the food - Foods and ingredients are known to cause hypersensitivity and shall always be declared - The presence in any food or food ingredients obtained through biotechnology of an allergen shall be declared - Added water shall be declared	- A list of APIs with the amount of each present in dosage unit - Statement of the net contents of the container - List of excipients known to be of safety concern for some patients
14	Origin and Retail Information	- Name and Complete Address of the Manufacturer - Net Quantity - Lot Number of Batch Identification - Date of Manufacture or Packing - Country of	- Name or description of food - Name and address of the local manufacturer, producer or importer - Country of	- A description of the food Information of the company responsible - Date Marking - Storage Conditions - Nutritional	- The Name of the Food Net Contents and Drained Weight - Name and Address - Country of Origin - Lot/Ba tch	- Name of the product - Indication of use - Storage conditions - Expiry date or product shelf life - Contraindication and any other

		Origin for Imported Food - Instructions for Use - Information Relating to Food Additives, Colours and Flavour - Veg or Non-Veg Symbol - Nutritional Information	origin of food - Date-marking of expiry date - Nutrition labelling	labelling	Identification - Date Marking and Storage Instructions - Instructions for Use	warnings -Directions of use, Manufacturer, packer or distributor's name and address - Quantity per dosage unit - List of any other ingredients and additive
Packaging Information						
15	Presentation requirement	The label must be in English or Hindi or Devnagri language	English	Shall be labelled in Bahasa Malaysia OR English AND may include translation in any other language.	English	English

7. Conclusion

Dietary supplements are playing very important role in various emerging countries so it is very important to regulate them in a correct manner. Therefore, this work will be helping in achieving that manner. Dietary supplements come mostly under the food umbrella so they usually do not have stringent regulations in any of the countries that have been mentioned above.

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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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