Guidelines for Regulating Health Supplements

DRA-G-D1-HS-06

Registration Division

Drug Regulatory Authority

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Version History

Version	Release Date	Version History	Revised By
00	31-01-2018	Original Release	FDIC
01	01-07-2021	Updated requirements pertaining to GMP & stability, permissible claims, heavy metals, microbial limits, NRV for vitamins and minerals and criteria for categorization of health supplements.	See list of contributors

Contents

1. Introduction

Health Supplements are known by various terminologies in different countries. They are often referred to as dietary supplements, nutrition supplements, complementary medicines etc. in different National Regulatory Authorities. In this Guideline, the term Health Supplement is used as a generic term inclusive of all the terminologies outlined above.

Due to the increased trend of manufacturers venturing into the Health Supplement market, there is unprecedented promotion and public interest in the use of such products. The Bhutan Medicines Board, taking note of such developments and challenges in monitoring consumers' safety, instructed the Drug Regulatory Authority (DRA) to regulate this category of product. Accordingly, Food and Drug Interface committee (FDIC) was also formed comprising of representatives from Bhutan Agriculture and Food Regulatory Authority (BAFRA), Office of Consumer Protection (OCP), Ministry of Health (MoH), Jigme Dorji Wangchuck National Referral Hospital (JDWNRH) and Bhutan Standards Bureau (BSB) to provide technical guidance to DRA.

This guideline is developed to guide the applicant in the preparation and submission of applications for listing health supplements. The Authority and the Food Drug Interface Committee adopts the principle of "Risk-based Approach" while evaluating health supplement applications.

This Guideline is broadly based on ASEAN Guidelines for regulation of Health Supplements. Certain annexures of the ASEAN Guidelines are identically adopted. Adoption of ASEAN Guidelines for regulation of Health Supplements was endorsed during the 17th Bhutan Medicines Board Meeting. For the purpose of clarity, this guideline contains both the regulatory requirements and procedures for listing of the Health Supplements.

2. Scope

2.1 This Guideline shall apply to products containing vitamins, amino acids and minerals (natural & synthetic) within the prescribed limits as per table 4; and

2.2 Substances derived from natural sources, including animal and plant materials in the form of extracts, concentrates and isolates.

2.3 However, this Guideline shall not apply to:

- 2.3.1 Product used as an essential ingredient of a meal or a diet;
- 2.3.2 Products used in alternative systems of medicine such as Homeopathy, Ayurveda, Unani and Siddha system of Indian Medicine;
- 2.3.3 Allopathic medicine;
- 2.3.4 Traditional Medicine;
- 2.3.5 Feed additives and supplements;
- 2.3.6 Herbal Medicine; and
- 2.3.7 Food for special dietary use.

3. Objective

4.1 To guide applicants in preparation and submission of applications for listing health supplements; and

4.2 To guide DRA and FDIC in listing health supplements.

4. Normative References

4.1 The following documents, in whole or in part, are normatively referenced in this guideline and are indispensable for its application.

- 4.1.1 The Medicines Act of the Kingdom of Bhutan 2003;
- 4.1.2 Bhutan Medicines Rules and Regulation 2019;
- 4.1.3 Annexure V: ASEAN Guidelines on Stability Study and Shelf Life of Traditional Medicines.

5. Definitions

5.1 **Act:** it refers to the Medicines Act of the Kingdom of Bhutan 2003.

5.2 **Adverse Reaction**: it refers to any noxious, undesired, or unintended response to a health supplement which occurs at a recommended amount.

5.3 **Authority**: it refers to the Drug Regulatory Authority.

5.4 **Assessment**: it refers to the evaluation of the application/label submitted by the applicant using a prescribed set of criteria.

5.5 **Claims:** it refers to any representation which states, suggests or implies that a product has particular qualities relating to its origin, nutritional/ functional/ disease risk reduction properties, nature, processing, composition or any other quality.

5.6 **Health Supplements (HS):** it refers to any product that is used to supplement a diet and to maintain, enhance and improve the health function of the 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, eye drops). It may contain one or more, or the following combination:

- 5.6.1 Vitamins, minerals, amino acids, fatty acids, enzymes, probiotics, and other bioactive substances;

5.6.2 Substances derived from *natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolite;

5.6.3 Synthetic sources of ingredients mentioned in (i) and (ii) may only be used where the safety of these has been proven.

5.7 **Listing:** it refers to the process of regulatory approval where DRA assesses the quality and safety of the product but not the efficacy.

5.8 **Market Authorization Holder:** it refers to the establishment having technical authorization for sale and distribution by wholesale or manufacturer or government agencies or body.

5.9 **Product:** it refers to Health Supplement products.

5.10 **Listing Certificate:** it refers to a document issued by the Authority in a prescribed format after the completion of assessment.

5.11 **Regulation**: it refers to Bhutan Medicine Rules and Regulations.

5.12 **Technical Authorization for Sale & Distribution:** it refers to the authorization issued to a local firm to deal in sale and distribution of products.

6. Acronyms

6.1 **DRA:** Drug Regulatory Authority

6.2 **FDA:** Food & Drug Administration

6.3 **FDI:** Food Drug Interface

6.4 **GMP:** Good Manufacturing Practices

6.5 **FDIC:** Food Drug Interface Committee

6.6 **CoA:** Certificate of Analysis

6.7 **ICMR:** Indian Council of Medical Research

6.8 **NRV:** Nutrient Reference Value

6.9 **RDA:** Recommended Dietary Allowance

7. General Principles

7.1 In accordance with section 16.2 of the Act and section 149 of the regulation, all health supplements shall require prior listing and import authorization from the Authority.

7.2 FDIC constituted under section 151 of the regulation, provides guidance for making informed decisions on the related products upon request from the concerned agencies or in the event of lack of clarity on the product categorization.

7.3 As per section 153 of the regulation, the Authority may draw a list of Health Supplements which are exempted from the listing requirements.

7.4 The Authority reserves the right to categorize the products into allopathic medicine, traditional medicine, herbal medicine or health supplements based on the claims and ingredients of the product.

7.5 Health Supplements does not include foods for special dietary uses or foods for special medical purposes or normal foods as the purpose of use differs.

7.6 Health Supplements shall be allowed in the dosage forms which includes but not limited to tablets, capsules, powder, granules, pills and liquid.

7.7 Notwithstanding section 7.5, injectable, sterile preparations and topical formulations shall not be considered as Health Supplements.

7.8 Health Supplements are not intended to diagnose, treat, mitigate or prevent any disease or disorder in human beings and are not to be marketed or presented or claimed as having such properties.

7.9 As per section 152 of the regulation, Health Supplements shall be categorized into three categories based on the product label/manual; Category (i) Nutrient/General Claim, (ii) Functional and (iii) Disease risk reduction claim.

7.10 For vitamins and minerals used in health supplements for 12 years and above, a minimum of 15% of the Codex Nutrient Reference Value (NRV) per daily dose of the vitamin(s) and/or mineral(s) will be required.

7.11 For vitamins and minerals used in health supplements for children 2-12 years of age, 15% of RDA value ICMR will be adopted.

7.12 Health Supplements shall be regulated using “risk based approach” and documentation requirement for listing shall be tagged with the category of the product it has been assigned to.

7.13 The listing of Health Supplements shall be conducted by the product registration committee constituted under the section 17.10 of the Act. However, in the event of ambiguities or listing of high risk products, FDIC or subject matter experts may be consulted.

7.14 The status of listing shall be appraised in the Drug Technical Advisory Committee.

7.15 The firms with valid Technical Authorization for sale and distribution or the concerned manufacturers shall only be eligible for listing of Health Supplement under category-II (functional products) & III (disease risk reduction products/claims).

7.16 All the firms licensed by the Ministry of Economic Affairs including grocery shops, firms with Technical Authorization for sale and distribution or the concerned manufacturers shall be eligible for listing of category I health supplements. All the firms authorized or licensed by the competent authority to manufacture, supply and sell goods shall be eligible for listing of category-I health supplements.

7.17 While the sale & distribution of category-I products shall not be restricted to licensed pharmacies, category-II and III products should be sold only through a licensed pharmacy or other authorized premises under the supervision of a competent person.

7.18 Listing certificate shall not be used as a marketing tool.

7.19 The manufacturer shall not be allowed to list same health supplement under different brand names.

7.20 Health Supplement shall not be labeled, advertised or promoted for any specific medicinal purpose against any disease or disorder or in such a way that potentially misleads the general public into believing that the product relates to any traditional healing paradigm, such as being a traditional medicine or allopathic medicine, when it is not intended as a traditional medicine or allopathic medicine.

7.21 Advertisement of Health Supplements shall require prior approval for advertisement from the Authority and the procedures shall be as per the Guidelines for Advertisement of Medical Products.

7.22 Good Manufacturing Practices certificate or equivalent certificates shall be required for listing of all categories of health supplements.

7.23 For category II and III health supplements, Certificate of Analysis (CoA) of at least two batches of finished product shall be required for listing Health Supplements.

7.24 The CoA should contain tests for heavy metals and microbial contaminations in addition to test for quality parameters described for the product.

7.25 Category III Health Supplements shall require a stability study report while category I and II are exempted from requirement of stability study report. However, for these categories evidence to substantiate its shelf life shall be submitted.

7.26 The regulatory approval shall be issued within 45 calendar days excluding the period when the application is kept on hold due to pending clarification or submission of evidence to substantiate claims/indication/intended use. In such cases, the applicant shall be informed.

7.27 An application for listing of Health Supplement shall be rejected on the following grounds:

7.27.1 If the product label contains prohibited ingredients included in the Table 1 of this guideline

7.27.2 If the product label contains objectionable terms and claims as Table 3 of this guideline.

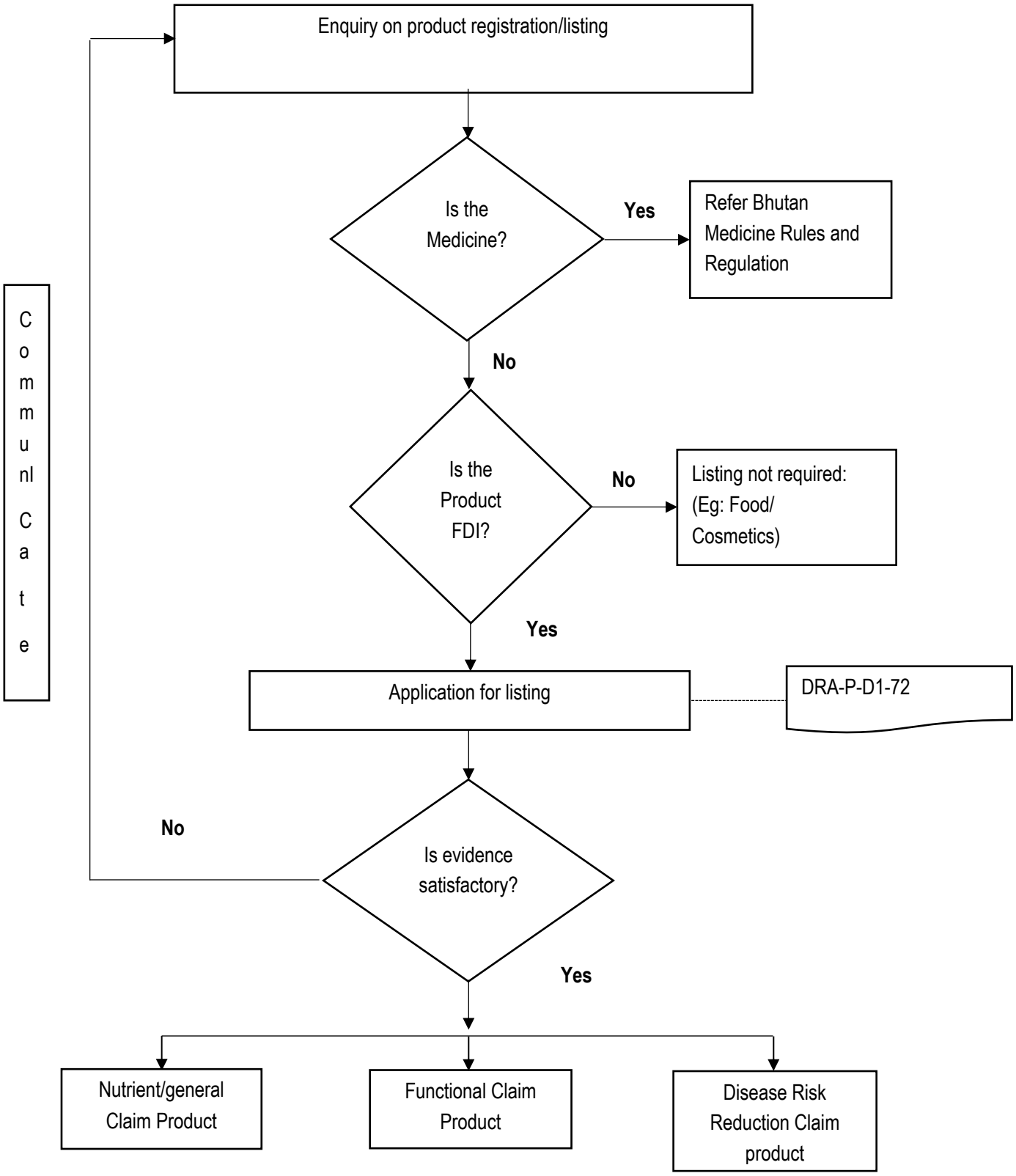
7.27.3 The application will be rejected and considered new if the applicant fails to complete the listing process within six months from the date of application.

7.28 The importer shall be responsible for ensuring safety, quality & effectiveness of the product and timely removal/recall from the Bhutanese market in case of product recalls.

7.29 The Technical Authorization Holders and importers shall notify the Authority in case of any variations on the label including indication/intended use and should strictly sell or distribute as per the categorization granted in listing certificate.

7.30 The Authority shall monitor any adverse reaction or side effects related to the use of the health supplements.

8. Process Flow for listing of Health Supplement



9. Procedure for Application

9.1 The application for listing of Health Supplement shall be made to DRA using the application form (Annexure 1 of this guideline) with the following documents:

- 9.1.1 Letter of authorization
- 9.1.2 Product Profile
- 9.1.3 Evidence to substantiate claims
- 9.1.4 Original product label/sample
- 9.1.5 Stability Study Reports (for category-III)
- 9.1.6 Evidence to justify shelf life (for category I & II)
- 9.1.7 Certificate of Analysis of Finished Product
- 9.1.8 cGMP or equivalent certificate

9.2 The application for listing must be accompanied by the application fee of Nu.500 (Five hundred only).

9.3 One product sample or original product packaging/labels should be submitted for the purpose of listing health supplements.

9.4 The Letter of Authorization from the manufacturer /distributor should contain a list of products authorized by the manufacturer or the distributor.

9.5 In case of a distributor authorizing the products to be listed, the letter of authorization should be accompanied by a dealership certificate.

9.6 The product profile should provide following information on the finished product:

- 9.5.1 Name/Brand name;
- 9.5.2 Dosage Form;
- 9.5.3 Strength of the product;
- 9.5.4 List of all ingredients in the dosage form and their amount on a per unit basis;
- 9.5.5 Description of the organoleptic characteristics of the product; including size, shape, superficial markings for identification purposes, colour, odour, taste,
- 9.5.6 Commercial presentation of packaging, label and packs consistency, type of tablet or capsules etc.; in terms of quantity/weight/volume etc; and
- 9.5.7 Intended use or claim for the product with directions for use.

10. Categorization of Health Supplements

10.1 Nutritional/General Claims

10.1.1 Refers to general health benefits derived from supplementation beyond a person's daily dietary intake.

10.1.2 Such claims are permitted only when the relevant vitamin and mineral used in the product amounts to a minimum of 15% of the Codex Nutrient Reference Value (NRV) per daily dose of the vitamin(s) and/or mineral(s). For example, if vitamin is less than 15% NRV, then the specific claim for this vitamin is not allowed unless there is evidence to support the effect below this value. (Refer Table 8).

10.1.3 Comparative nutrient claims which use words like 'better than', 'richer than', or 'equivalent to' etc. are not permitted.'

10.2 Functional Claims

10.2.1 Relate to a positive contribution to a function or biological activity of the body.

10.2.2 Maintains or enhances structure or function of the body, excluding disease related claims.

10.2.3 Such claims are permitted only when the relevant vitamin and mineral used in the product amounts to a minimum of 15% of the Codex Nutrient Reference Value (NRV) per daily dose of the vitamin(s) and/or mineral(s). For example, if vitamin is less than 15% NRV, then the specific claim for this vitamin is not allowed unless there is evidence to support the effect below this value.

10.2.4 The distributor must provide with the text of the claim to the authority when required to do so. This product is not intended to diagnose, treat, cure, or prevent any disease.

10.3 Disease Risk Reduction Claims

10.3.1 Relate to significant alteration or reduction of a risk factor of a disease or health related condition. Example, "helps to reduce risk of osteoporosis by strengthening bone, helps to reduce risk of dyslipidemia.

10.3.2 Claims associated with certain diseases such as but not limited to cancer, aphrodisiac, abortifacient, blindness, sexual impotence, obesity, mental disorder, STDs and HIV/AIDS shall be strictly prohibited for listing.

11. Evidence to Substantiate Claims

In general, claims should not be false, misleading or imply to treat or cure any disease or condition. All claims mentioned on product labels or product brochures must be substantiated with evidence. The evidence must be specific to claims as mentioned on the product label or product brochure.

Category of Health Supplement	**Examples/ Wording of claim**	**Evidence to substantiate claims**
General Or Nutritional Claims	▪Supports healthy growth and development ▪Nourishes the body ▪Relieves general tiredness and weakness ▪Helps to maintain good health ▪For energy and vitality ▪For strengthening the body	1 or more of the following evidences: i. Standard reference e.g. reference textbooks, pharmacopoeia, monographs or; ii. Approval of product from reference regulatory authorities or; iii. Recommendations on usage from reference organizations.
Functional Claims (medium)	Acceptable claims based on the single ingredient. e.g. ▪ Vitamin A helps to maintain growth, vision and tissue development ▪ Vitamin D helps in normal development and maintenance	1 or more of the following evidences: i. Standard reference e.g. reference textbooks, pharmacopoeia, monographs or; ii. Approval of product from reference regulatory authorities or; iii. Recommendations on usage from reference organizations or;

	of bones and teeth. ▪ Chondroitin helps to promote healthy joints.	iv. Good quality scientific evidence from human observational studies (only in the event that human experimental study is not ethical, animal studies will be accepted together with epidemiological studies or other scientific literature and documented traditional use) v. Peer-reviewed scientific data or meta-analysis
Disease risk reduction	▪ Helps to reduce risk of Osteoporosis by strengthening bone ▪ Helps to reduce the risk of dyslipidemia	Mandatory evidence: i. Scientific evidence from human intervention study on ingredient and/or product ii. Toxicological study (chronic) iii. Pharmacological study At least 1 additional evidence: Standard reference e.g. reference textbooks, pharmacopoeial monographs etc. iv. Approval of the product from reference regulatory authorities or; v. Recommendations on usage from reference organizations. vi. Published scientific reviews or meta-analysis

12. Claims Substantiation

12. 1 Claims must be in line with the respective Health Supplement principles and supported by adequate evidence. A summary of the evidence with following information shall be submitted:

- 12.1.1 Indication/claim
- 12.1.2 Product
- 12.1.3 Ingredient
- 12.1.4 Dosage and route of administration
- 12.1.5 Duration of treatment
- 12.1.6 Type of scientific evidence
- 12.1.7 Study design
- 12.1.8 Study population
- 12.1.9 Summary of the findings
- 12.1.10 Limitation of study
- 12.1.11 Source of evidence (Author, Title, publication details, year, type)

13. Acceptable Reference Texts/ Organizations/ Regulatory Authorities

13.1 **Reference Texts**

- 13.1.1 Martindale, latest edition The Complete Drug. Pharmaceutical Press, 2009
- 13.1.2 The ABC Clinical Guide to Herbs. American Botanical Council
- 13.1.3 WHO Monographs on Selected Medicinal Plants
- 13.1.4 British Pharmacopoeia
- 13.1.5 United States Pharmacopoeia
- 13.1.6 Indian Pharmacopoeia
- 13.1.7 Chinese Pharmacopoeia
- 13.1.8 Natural Standards (www.naturalstandard.com)
- 13.1.9 Office of Dietary Supplements, National Institutes of Health - Dietary Supplement Fact Sheets (http://ods.od.nih.gov/Health_Information/Information_About_Individual_Dietary_Supplements.aspx)

13.2 **Publications from Organizations**

- 13.2.1 American Botanical Council (www.herbalgram.org).
- 13.2.2 American Nutraceutical Association (www.ana-jana.org)
- 13.2.3 CODEX Alimentarius
- 13.2.4 Global Information Hub for Integrated Medicine (http://www.globinmed.com)
- 13.2.5 National Centre for Complementary and Alternative Medicine (http://nccam.nih.gov/)
- 13.2.6 Office of Dietary Supplements, National Institutes of Health (USA) (http://ods.od.nih.gov)

13.3 **Reference regulatory authorities**

- 13.3.1 PIC/S member country
- 13.3.2 Chinese Health Authority on Chinese medicinal herbs

Notes:

1. *This list is not meant to be exhaustive and will be reviewed from time to time.*
2. *The Authority will nonetheless conduct a detailed evaluation of the evidence included in the report to ensure that the health claim is substantiated.*
3. *The Authority will be willing to consider review other than the ones listed above, if the standards of evidence are consistent with those of the Authority.*
4. *All references must be current.*

14. Labeling Requirements

14.1 Health Supplement shall not be described or presented on any label or in any labeling in a manner that is false, misleading or deceptive or is likely to create an erroneous impression regarding its character in any aspect.

14.2 Health Supplement shall not be described or presented on any label or in any labeling by words, pictorial or other devices which refer to or are suggestive either directly or indirectly, of any other product.

14.3 The content on the label should be legible.

14.4 The label must not contain objectionable terms as listed in table 3.

14.5 The label information should be English and/or Dzongkha

14.6 The Authority reserves the right to disallow any other words, phrases or graphics for product labels which in its opinion are misleading, improper or not factual.

14.7 For vitamins and minerals, the amount shall be declared in metric units (gram or milligram or microgram) and International Units.

14.8 The following minimum information should be available on the label:

14.8.1 Product Name (generic/ brand name)
14.8.2 Dosage Form
14.8.3 Name and Strength of Active ingredient
14.8.4 Batch or Lot Number
14.8.5 Manufacturing and expiry date or Expiry date only
14.8.6 Directions of use
14.8.7 Indication or Intended use
14.8.8 Storage condition.
14.8.9 Name and address of manufacturer
14.8.10 Pack Size
14.8.11 NRV for vitamins/ minerals used as food/ dietary supplements
14.8.12 “Health supplement / dietary supplement”
14.8.13 Cautionary statement, if any.

14.9 For products containing ingredients of animal origin(s), please add this statement: "**This product contains substance(s) from animal origin".**

14.10 In the event, when the size of the primary packaging of the health supplement is too small to accommodate information stated in 6.6.3, the label should at least include information on:
- 14.10.1 Product name
- 14.10.2 Batch or Lot number
- 14.10.3 Manufacturing or expiry date
- 14.10.4 Name of the manufacturer

14.11 However, all the other information stated in 6.6.3 should be stated on secondary product label or product insert.

15. Stability Data.

15.1 The stability study should be provided for Category III- (Disease Risk Reduction Claim) products.
15.2 The design of a stability study for the product should be based on the nature of the product.
15.3 Stability data from at least two batches will be required, derived either from pilot scale, primary scale, production scale or their combination.
15.4 Stability studies should be conducted on individual strengths of the product and/or type of container closure system in which the finished product is packed.
15.5 Stability study should be conducted as per ASEAN Guidelines on Stability Study and Shelf Life of Health Supplements.

Table 1: List of Prohibited Ingredients

Scientific Name & Photos	Common name(s)	Harmful Animal/plant parts	Name of Harmful Compound or Compound Classes
***Abrus precatorius* L.**	Indian Licorice, Precatory bean, Jequerity, Mutual, love Bean (China), Kudri Mani, (Tamil), Guru Ginja (Telegu)	Seed	Abrin, which consists of abrus, agglutinin, and toxic lectins, abrins
Aconitum spp. *(all species) containing aconite alkaloids*	Monkshood, Aconite	Whole plant	Aconite alkaloids
***Adonis vernalis* L.**	Pheasant's eye	Whole plant	Adonitoxin
Animal parts containing hormones (all species)		Parts that may contain hormones: Pituitary gland, Thyroid gland, Parathyroid glands, Adrenal	Growth hormone, prolactin, adrenocortico-tropic hormone, Thyroid-stimulating hormone, Follicle-stimulating hormone, luteinizing hormone, oxytocin, Antidiuretic hormone, thyroid hormone, calcitonin, Parathyroid hormone, mineralocorti-coids, glucocorti-coids, sex hormones, insulin, glucagon, thymosin, estrogens, progesterone, testosterone
***Antiaris toxicaria* Lesch.**	Upas tree (Javanese Language- arrow poison), Bark cloth Tree		Cardiac glycoside (antiarin), Cardenolides & Alkaloids (with cardiac arresting potential)
***Aristolochia* spp.** (all species) containing aristolochic acid	Birthwort, Pelican flower, Sangree root, Sangrel, Serpentaria, Snakeroot,	Whole plant	Aristolochic acid

	Snakeweed		
***Artemisia* spp.** (all species containing artemesinin)	Wormwood	Leaf	Artemisinin
***Aspidosperma quebracho-blanco* Schltdl.**	Quebracho	Bark	Aspido-spermine
***Atropa belladonna* L.**	Deadly Nightshade	Whole plant	Scopolamine; Hyoscyamine; Atropine
***Azadirachta indica* A.Juss.**	Nimba, Neem	Seeds	Azadirachtin and derivatives
***Berberis* spp. (all species) containing berberine e.g. *Berberis vulgaris* L.**	Mahonia Aquifolium: Oregon Grape , Mountain Grape, Barberry. Mahonia Repens: Creeping Barberry, Creeping Mahonia, Creeping Oregon-Grape Mahonia Nervosa: Dwarf Oregon-grape, Cascade Oregon-grape, Dull Oregon –grape	Root, bark, rhizome	Berberine
***Brucea javanica* (L.) Merr.**	Sumatrana amarissimus, Java brucea	Dried fruits & seed	Bruceine, Bruceantinol and Bruceoside
***Bufo gargarizans* Cantor** ***Bufo melanostictus* Schneider** ***Bufo vulgaris* Lour.**	Toad, Samsu, kodok kerok	Venom, dried, secretion, whole body	Cinobufagin, resibufagenin, bufagins, catecholamines: asbufothionine
***Calotropis gigantea* (L.) Dryand.** ***Calotropis procera* (Aiton) Dryand.**	Crown flower, Giant milkweed	Latex	Cardiac glycosides, calotropin
***Cannabis sativa* L.** ***Cannabis indica* Lam.**	Marijuana	Whole plant	Cannabinoids
***Catharanthus roseus* (L.) G.Don**	*Vinca rosea*, Periwinkle Madagascar, Old Maid	Whole plant	Vinca alkaloids
***Cerbera manghas* L.**	Dog bane, Pink eyed cerbera	Seed	Digitoxinglyco-side, Cerberine, Cerberoside, thevetin
***Cerbera odollam* Gaertn.**	Indian Suicide Tree,	Seed	Cerberin, cerebroside, odollin, odolotoxin,

	Sea Mango		thevetin and cerapain.
***Chelidonium majus* L.**	Celandine, Great Celandine, Nipplewort	Dried, whole or cut aerial parts	Berberine, chelidonine, sanguinarine, coptisine, chelerythrine
***Chondrodendron tomentosum* Ruiz & Pav.**	Curare	Stems	Tubocurarine chloride
***Cinchona* spp.**	Quine bark	Bark	Cinchona alkaloids ex. Quinine and Derivatives
***Citrullus colocynthis* (L.) Schrad.**	Bitter apple	Seed, fructus	Curcubitacin
***Claviceps purpurea* (Fr.) Tul.**	Ergo	Sclerotium	Ergot alkaloids (including ergotamine and ergometrine)
***Colchicum autumnale* L.**	Meadow Saffron	Seed	Cochicine
***Conium maculatum* L.**	Hemlock	Whole plant	Coniine
***Croton tiglium* L.**	Croton	Fruit, seeds and oil	Croton oil containing: Crotonic acid, tiglic acid, crotin, cocarcinogen Phorbol ester
***Datura* spp.** (all species) containing hyoscyamine, atropine, scopolamine and apoatropine	Jimson weed, Devil's apple, Green Dragon, Zombie's Cucumber, Moon Weed, Trumpet Lily, Stinkweed	Leaf, seed, flowering or fruiting parts with branches	Hyoscyamine, atropine, scopolamine, apoatropine
***Delphinium staphisagria* L.**	Stavesacre	Seeds	Delphinine, Staphisine
***Digitalis* spp.** (all species) containing glycoside	-	Leaf	Cardiac glycoside

***Drimia maritima* (L.) Stearn** **Syn. *Urginea maritima* (L.) Baker**	Sea squill, red squill, sea onion, squill	Bulb	Cardiac glycoside
***Dryobalanops sumatrensis* (J.F.Gmel.) Kosterm.** **Syn. *Dryobalanops aromatica* C.F.Gaertn.**	Borneo camphor, Kapur, Malay Camphor, Sumatra camphor	Whole plant	Borneol (Borneo camphor)
***Dryobalanops lanceolata* Burck**			
***Dryopteris filix-mas* (L.) Schott**	Male Fern, aspidium, Male Shield Fern	Rhizome	Filicin, aspidinol
***Euphorbia antiquorum* L.*Euphorbia trigona* Mill.**	Triangular spurge	Latex	Alpha euphorbol, Beta amyrin cycloartenol Euphol
***Fritillaria* spp.**	Fritillary bulb	Dried bulb	Alkaloid: chinpeimine, fritimine, beilupeimine hashimirine peimine
***Garcinia elliptica* Wall. ex Wight** ***Garcinia hanburyi* Hook.f.** ***Garcinia morella* (Gaertn.) Desr.**	Gamboge	Gum resin	Cambogic acid, β-guttiferin, α-1-guttiferin
***Gelsemium elegans* (Gardner & Chapm.) Benth. *Gelsemium sempervirens* (L.) J.St.-Hil.**	Palaung Thay	Root, leaves and rhizomes	Gelsemine & Gelseminine (Gelsemium indole
***Gluta usitata* (Wall.) Ding Hou** **Syn. *Melanorrhoea usitata* Wall.**	Vanish tree	Latex	Urushic acid, Urushiol, Cardanol, Cardol, Anacardic acid
***Hyoscyamus muticus* L.** ***Hyoscyamus niger* L.**	Henbane, Henblain, Jusquaime	Whole plant	Hyoscyamine, atropine, hyoscine
***Jatropha multifida* L.**	Coral Bush, Coral Plant, Physic nut, Guatemala	Fruits/Seeds	Phytotoxin (Toxalbumin - Curcin)

	Rhubarb		
***Juniperus sabina* L.**	Savin, Savine	Extracted Essential oil (i.e. Savin Oil)	Sabinyl acetate, sabinene, podophyllo-toxin and others
***Lantana camara* L.**	Tembelekan (tahi ayam)	Whole plant	Lantadene 2,2% from dry leave and stem Lancamaron
***Larrea tridentata* (Sessé & Moc. ex DC.) Coville, *Larrea mexicana* Moric.**	Chaparral	Whole plant	Main harmful compounds in chaparral are Lignans, in which nordihydro-guaiaretic acid (NDGA) is the major compound
***Lobelia nicotianifolia* Roth ex Schult.** ***Lobelia inflata* L.** ***Lobelia chinensis* Lour.** ***Lobelia tupa* L.**	Indian Tobacco	Whole plant	Lobeline
***Lytta vesicatoria* Linn.**	Spanish flies	Whole body, tinktur	Cantharidin
***Magnolia officinalis* Rehder & E.H.Wilson**	Houpo, Houpohua, Lamp post, Officinal magnolia	Whole plant	Bark:level of magnolol 2-11%, honokiol 0.3-4.6%,eudes mol <1%, < 200mg of bark/dosage form has to be from a Chinese formulation and contraindicated in pregnancy (emmena-gogue)
***Melaleuca alternifolia* (Maiden & Betche) Cheel**	Tea tree oil (TTO)	Tea tree oil	Tea tree oil
***Mitragyna speciosa* (Korth.) Havil.**	Kratom	Whole plant	Mitragynine indole, alkaloid
***Mucuna pruriens* (L.) DC.**	Cowhage, Cowage	Seed	Dopamine, Nicotine, Physostigmine
***Mylabris phalerata* Pall.** ***Mylabris cichorii* Linnaeus**	Blister beetle, Mylabris	Dried body	Cantharidin
***Nerium oleander* L.** **Syn. *Nerium indicum* Mill.**	Indian oleander, Exile Tree	Whole plant	Neriin

***Nicotiana tabacum* L.**	Tobac	Leaf	Nicotine
***Papaver* spp.** (all species) containing morphine & derivatives and codeine	Opium poppy	Whole plant	Morphine and derivatives, codeine
***Pausinystalia johimbe* (K.Schum.) Pierre ex Beille**	Yohimbe	Bark	Yohimbine
***Physostigma venenosum* Balf.**	Calabar bean	Seed, bean	Physostigmine
***Pilocarpus microphyllus* Stapf ex, Wardleworth *Pilocarpus jaborandi* Holmes *Pilocarpus pinnatifolius* Lem.**	Jaborandi	Bark	Pilocarpine
***Piper methysticum* G.Forst.**	Kava Kava	Whole plant	Pyrones, ethanol extract
***Plumbago zeylanica* L.**	White leadwort	Roots	Plumbagin
***Plumbago indica* L.**	Rose-coloured leadwort	Root, root bark	Plumbagin
***Podophyllum emodii* Wall. ex Hook.f. & Thomson *Podophyllum peltatum* L.**	American mayapple, Mandrake	Roots, leaves	Podophyllin resin
***Psilocybe cubensis* (Earle) Singer**	Boomers, Gold caps	Whole plant	Psilocybine, Psilocin
***Punica granatum* L.**	Pomegranate	Stem bark and root bark	Pomegranate alkaloids
***Rauvolfia serpentina* (L.) Benth. ex Kurz Syn. *Ophioxylon serpentinum* L. *Rauvolfia vomitoria* Afzel.**	Rauwolfia, Indian snakeroot, Snakeroot	Root, whole plant	Reserpine, Rescinnamine, ajmalane
***Sanguinaria canadensis* L.**	Bloodroot, Indian Paint	Rhizomes and roots	Sanguinarine, chelerethrin, sanguirulin, berberine, protopine
***Schoenocaulon officinale* (Schltdl. & Cham.) A.Gray**	Sabadilla	Seed	Veratrine
***Scilla sinensis* (Lour.) Merr.**	-	Bulb	Cardiac glycoside
***Senecio aureus* L.**		Whole plant	Pyrrolizidine alkaloids

***Senecio jacobaea* L.** ***Senecio bicolor* Sch.Bip.** ***Senecio nemorensis* L.** ***Senecio vulgaris* L.** ***Senecio longilobus* Benth.**			
***Solanum dulcamara* L.** ***Solanum americanum* Mill.** **Syn. *Solanum nigrum* L.**	Bittersweet, Nightshade	Leaf, flowering tops	Solanaceous alkaloids
***Sophora tomentosa* L.**	Sea coast Laburnum, Silver Bush	Seed	Spigeline (a strychinine-like alkaloid)
***Stephania tetrandra* S.Moore**	Fang ji, Fen fang ji,Han fang ji Stephania-root	Whole plant	Aristolochic acid
***Strophanthus* spp.** (all species) containing strophanthus alkaloids	Kombe	Whole plant	Strophanthus alkaloids
***Strychnos nux-vomica* L.** ***Strychnos ignatii* P.J. Bergius** ***Strychnos lucida* R.Br.** ***Strychnos roborans* A.W.Hill**	Nux-vomica	Seed	Strychnine
Symphytum officinale* L.** ***Symphytum asperum* Lepech.** ***Symphytum × uplandicum* Nyman** ***Symphytum peregrinum **Ledeb.**	Comfrey	Whole plant	Pyrrolizidine alkaloids
***Veratrum viride* Aiton** ***Veratrum album* L.** ***Veratrum mengtzeanum* O.Loes.** ***Veratrum nigrum* L.** ***Veratrum stenophyllum* Diels** ***Veratrum maackii* Regel,**	American Hellebore, Indian Poke, Indian Hellebore, False Hellebore, Green False Hellebore, White Hellebore	Whole Plant	Veratrum alkaloids including veratramine, cyclopamine, cycloposine, jervine, and muldamine
***Vinca minor* L.**	Periwinkle, Myrtle	Whole plant	Indole alkaloids: Vincamine, eburnamenine

Dehydroepiandrosterone (DHEA)			(Not to be used in health supplements. It is a steroid. Known to increase risk of certain cancers.)
Dimethylamylamine (DMAA)			(Not to be used in health supplements. It is a synthetic chemical. Known to have adverse effects on the heart and circulatory system).
1.Beta-phenyl-delta-amino butyric acid (Phenibut)			
2.Coenzyme-Q10-Ubiquinone Ubidecarenone (Restricted to 150mg per day.			Concomitant use with warfarin might reduce the anticoagulation effects of Warfarin. The following cautionary label or similar wording is required: “Do not take while on Warfarin therapy without medical advice.”.)
Corydalis ambigua, C. bulbosa, C. amurensis, C. decumbens, C. pallida, C. racemosa, C. turschaninorii, C. yanhusuo (Not to be used in health supplements. Known as a sedative, with effects on the central nervous system.)			
Danthron			

Dehydroepiandrosterone (DHEA)			(Not to be used in health supplements. It is a steroid. Known to increase risk of certain cancers.)
Dimethylamylamine (DMAA)			(Not to be used in health supplements. It is a synthetic chemical. Known to have adverse effects on the heart and circulatory system).
Dimethyl sulphoxide (DMSO)			(Not to be used in health supplements. Typically used as a chemical solvent.)
Dimethylaminoethanol (DMAE)			(Not to be used in health supplements. known to cause various adverse effects in the body, such as insomnia and depression.)
1, 3-dimethylbutylamine (DMBA)			(Not to be used in health supplements. It is a synthetic chemical. Known to raise blood pressure.)
Ephedra sinica (Ma Huang), Sida cordifolia			(Not to be used in health supplements. Known to cause adverse effects on the heart and circulatory system.)
Ginkgo biloba (leaf)			*(*Concomitant use with blood thinning medicines may increase risk of bleeding. The following cautionary label or similar wording is required:

Hydrastis canadensis (Golden Seal), Berberis vulgaris (Barberry), Berberis aquifolium (Oregon Grape), Coptis chinensis (Chinese goldthread), Coptis teeta, Mahonia aquifolium, M. repens, M. nervosa, Phellodendron amurense, P. chinense,			(Not to be used in health supplements. Restricted for use in Chinese Proprietary Medicines only.)
Lagandrol			(Not to be used in health supplements. It is a synthetic chemical developed for use in medicines.)
Lithium and its salt			Not to be used in Health supplements. Known to cause kidney, nerve and cardiovascular abnormalities)
N-acetylcysteine			(Not to be used in health supplements. It is a synthetic chemical developed for use in medicines.)
Pangamic acid and its salt			(Not to be used in health supplements. Known to cause adverse effects on the liver.)
Pituitary gland, Somatropin, Human Growth hormone, Suprarenal gland, Thyroid gland, Sex hormones, Androstenedione etc			

Polygoni multiflori (root) (He Shou Wu)			(Known to cause liver side effects. The following cautionary label or similar wording is required:"Polygoni multiflori may cause liver problems. Seek medical advice before use."
Prunus armeniaca, Amygdalus armeniaca, Armeniaca vulgaris			Not to be used in health supplements. Known to cause cyanide poisoning.)
Monascus purpureus (Red Yeast Rice) Lovastatin (active constituent) **(**Restricted to less than 1% lovastatin. Known to cause body and muscle aches. The following cautionary label or similar wording is required: "This product contains naturally-occurring lovastatin. Seek medical advice before use if you are already taking cholesterol-lowering medicines. Discontinue use of the product if you experience muscle aches or weakness."			
Aniracetam, Oxiracetam, Pramiracetam, Phenylpiracetam (Fonturacetam)			(Not to be used in health supplements. These are synthetic chemicals developed for use in medicines.)
Senna alexandria, Cassia angustifolia, Cassia senna (Senna)			(Known to cause cramping, diarrhea and loss of essential minerals. The following cautionary label or similar wording is required: "*This product contains sennosides. Prolonged use may cause serious bowel problems and loss of essential minerals. Seek medical advice*

			for use beyond 1 to 2 weeks.".)
Silver and its salt.			(Not to be used in health supplements. Known to cause permanent grey to blue-black discoloration to the skin, mucous membranes and eyes.)
Testolone			(Not to be used in health supplements. It is a synthetic chemical. Known to cause heart attack, stroke and liver damage.)
Vitamin K1 (phylloquinone, phytomenadione, phytonadione) Vitamin K2 (menaquinone, menatetrenone)			(Restricted to oral dosage forms of multi-vitamin/mineral preparations for adults with maximum limit of 120mcg per day for general health. The following cautionary label or similar wording is required : "Consult a healthcare professional prior to use if you are taking a blood thinner such as warfarin.".)
Vitamin K3 (menadione)			Not to be used in health supplements. It is a synthetic chemical. Known to be associated with neonatal hemolysis and liver damage.)

Note 1: table 1 is adopted from appendix 2: Annexure I ASEAN Guiding Principles for Inclusion into or exclusion from the negative list of substances for traditional medicines and Health Supplements and Health Supplement Guidelines 2020, Health Sciences Authority.

TABLE 2: RECOMMENDED DIETARY ALLOWANCES FOR INDIANS

Group	Particulars	Body weight kg	Net energy Kcal/d	Protein g/d	Visible fat g/day	Calcium mg/d	Iron mg/d	Vitamin mg/kg		Thiamine mg/d	Riboflavin mg/d	Nicotinic acid mg/d	Pyridoxinemg/d	Ascorbic acid mg/d	Free folic acid mg/d	Vit B12 mg/d
								Retinol	b carotene							
Man	Sedentary work	60	2425	60	20	400	28	600	2400	1.2	1.4	16	2.0	40	100	1
	Moderate work		2875							1.4	1.6	18				
	Heavy work		3800							1.6	1.9	21				
Woman	Sedentary work	50	1875	50	20	400	30	600	2400	0.9	1.1	12	2.0	40	100	1
	Moderate work		2225							1.1	1.3	14				
	Heavy work		2925							1.2	1.5	16				
	Pregnant woman	50	+ 300	+15	30	1000	38	600	2400	+0.2	+0.2	+2	2.5	40	400	1
	Lactation															
	0-6 months	50	+550	+25	45	1000	30	950	3800	+0.3	+0.3	+4	2.5	80	150	1.5
	6-12 months		+400	+18						+0.2	+0.2	+3				
Infants	0-6 months	5.4	108/kg	2.05/kg		500		350	1200	55mg/kg	65mg/kg	710mg/kg	0.1	25	25	0.2
	6-12 months	8.6	98/kg	1.65/kg						50mg/kg	60mg/kg	650mg/kg	0.4			
Children	1-3 years	12.2	1240	22	25	400	12	400	1600	0.6	0.7	8	0.9	40	30	0.2-1.0
	4-6 years	19.0	1690	30			18	400		0.9	1.0	11			40	
	7-9 years	26.9	1950	41			26	600	2400	1.0	1.2	13	1.6		60	
Boys	10-12 years	35.4	2190	54	22	600	34	600	2400	1.1	1.3	15	1.6	40	70	0.2-1.0
Girls	10-12 years	31.5	1970	57			19			1.0	1.2	13				
Boys	13-15 years	47.8	2450	70	22	600	41	600	2400	1.2	1.5	16	2.0		100	0.2-1.0

Girls	13-15 years	46.7	2060	65			28			1.0	1.2	14				
Boys	16-18 years	57.1	2640	78	22	500	50	600	2400	1.3	1.6	17	2.0	40	100	0.2-1.0
Girls	16-18 years	49.9	2060	63			30			1.0	1.2	14				

Source : Gopalan. C, Rama Sastri B.V. and Balasubramanian, S.C., 2004, Nutritive Value of Indian Foods, National Institute of Nutrition, ICMR, Hyderabad.

Table 3: List of objectionable terms and claims

1. Miraculously
2. The only product to use
3. World's best
4. 100% safe
5. No side effects
6. Guaranteed
7. Other drugs/products cannot compare with it
8. Sensational relief
9. The number one (unless substantiated)
10. Efficacious/effective
11. Perpetual youth
12. Anti-ageing (unless substantiated)
13. Longevity
14. Anti-stress (unless substantiated)
15. Breast enhancement, enlargement, growth
16. Height growth
17. Enhance IQ/intelligence
18. Increase/improve memory
19. Enhancement of sexual organs
20. Sexual power
21. Arousal and libido

Note: Table 3 is adopted from page 12 on examples of objectionable terms and claims, Health Supplements Guidelines, Revised August 2017, Health Sciences Authority, Singapore

Table 4: Maximum Levels of Vitamins & Minerals in Health Supplements.

Vitamin	Maximum Level	Minerals	Maximum Level
Vitamin A (Retinol)	1.5 mg/day (5000 IU/day)	Calcium	1200 mg/day
Vitamin D	0.025 mg/day (1000 IU/day)	Phosphorus	800 mg/day
Vitamin E	536 mg/day (800 IU/day	Magnesium	350 mg/day
Vitamin K	0.12 mg/day	Boron	6.4 mg/day
Vitamin C	1000 mg/day	Chromium	0.5 mg/day
Vitamin B1	100 mg/day	Copper	2 mg/day
Vitamin B2	40 mg/day	Iodine	0.15 mg/day
Vitamin B6	100 mg/day	Iron	15 mg/day
Folic acid	0.9 mg/day	Manganese	3.5 mg/day
Vitamin B12	0.6 mg/day	Molybdenum	0.36 mg/day
Biotin	0.9 mg/day	Selenium	0.2 mg/day
Nicotinic acid	15 mg/day	Zinc	15 mg/day
Nicotinamide	450 mg/day		
Pantothenic acid	200 mg/day		

Note : Table 4 is adopted from Appendix I, Annexure X ASEAN Maximum Levels of Vitamins & Minerals in Health Supplements.

Table 5: Heavy Metals Limits

Heavy Metal	Quantity (by Weight)
Arsenic	5ppm
Cadmium	0.3ppm
Lead	10ppm
Mercury	0.5ppm
Copper	150ppm

Table 6: Microbial Limits

Microbe	Quantity (CFU/g or ml)
Total aerobic microbial count	NMT 10^5
Yeast and Mold Count	NMT 5x10^2
E.coli, Salmonellae and S.aureus	Should be absent

The above limits for total aerobic microbial count, and yeast and mold may not be applicable to certain products such as probiotics or products derived from fermentation processes.

Note:

Table **5** and **6** adopted from Health Supplement Guidelines 2020, Health Sciences Authority, Singapore

Table 7: NRVs for Vitamins Minerals

S.No	Vitamin/Minerals	CODEX NRV
1	Vitamin C	100mg
2	Vitamin K	60mcg
3	Vitamin D	5-15mcg
4	Vitamin A	800mcg
5	Vitamin E	9mg
6	Thiamine	1.2mg
7	Riboflavin	1.2mg
8	Niacin	15mg
9	Vitamin B6	1.3mg
10	Folate	400mcg
11	Vitamin B12	2.4mcg
12	Pantothenate	5mg
13	Biotin	30mcg
Minerals		
1	Calcium	1000mg
2	Iron	14-22mg
3	Magnesium	310mg
4	Selenium	60mcg
5	Phosphorus	700mg
67	Copper	900mcg

8	Molybdenum	45mcg
9	Manganese	3mg
10	Zinc	11-14mg
11	Iodine	150mcg
Others		
1	Protein	50g

Note: Table 7 is adopted from Appendix 1, Guidelines on Nutrition Labelling, CODEX Nutrient Reference Values, Food and Agriculture Organization of the United Nations and World Health Organization.

Table 8: List of Health Supplement Claims

Health Supplements may make claims that support or maintain health, well-being or physiological process. These claims can be classified as general claims, or specific claims to maintain or enhance a specific body function or structure. The list below can be used as a general guide on permissible health supplement claims.

PERMISSIBLE GENERAL/ NUTRITIONAL CLAIMS
For general health/health support/health maintenance Support/promote/maintain health A factor in the maintenance of good health Provides/source of antioxidants for maintenance of good health For healthy growth and development Helps normal growth and development Provides/Source of fatty acids/omega acids for the maintenance of good health
PERMISSIBLE SPECIFIC FUNCTIONAL CLAIMS
For cardiovascular/circulatory health Support/promote blood circulation
For healthy blood circulation Support peripheral circulation Support/promote/maintain heart/cardiovascular health For a healthy heart and cardiovascular system
For gastric/ digestive health Support/promote/maintain healthy digestion Support/promote/maintain digestive health/digestive system/gut Source of fiber for the maintenance of good digestive health As a digestive aid/ Support regular bowel movements Support/promote/maintain liver health
For immune support For immune health Support/promote/maintain immune health
For exercise performance Support/maintain/promote vitality Support/promote physical performance Helps to overcome/relieve general weakness/fatigue/tiredness Support/promote/maintain healthy muscles
SPECIFIC HEALTH CLAIMS
For urinary health Support/promote/maintain urinary health

For bone and joint health Support/promote/maintain joint health/healthy joints Support/promote/maintain bone health/healthy bones Support/promote/maintain joint cartilage
For eye and skin health Support/maintain eye health/healthy vision Support/promote/maintain healthy complexion Support/promote/maintain healthy skin/hair/nails
PERMISSIBLE DISEASE RISK REDUCTION CLAIMS
Helps to reduce risk of osteoporosis by strengthening bone Helps to reduce the risk of dyslipidemia

Note: Table 8 is adopted from Health Supplement Guideline, (revised June 2020) Health Sciences Authority, Singapore

Table 9: Permissible claims for specific active ingredients in HS products

Ingredients	Claims		
	General	**Functional**	**Disease risk reduction**
Vitamin A	● Maintenance of good health	● Helps to maintain growth, vision and tissue development ● Aids in maintaining the health of the skin and mucous membrane	
Vitamin C		● For healthy bones, (cartilage), teeth, gums as well as general make-up of the body	
Vitamin D	● Maintenance of good health	● Helps in normal development and maintenance of bones and teeth ● Helps the body utilize calcium and phosphorus ● Claim for specific population subgroups: Elderly people who are confined indoors	
Vitamin E	● Maintenance of good health		

Beta Carotene	● Maintenance of good health	● Helps in maintenance of growth, vision and tissue differentiation	
Vitamin B1 (Thiamine)	● Helps to maintain good health	● Helps in maintenance of growth, vision and tissue differentiation	
Riboflavin (Vitamin B2)	● A factor in maintenance of good health	● Helps the body to utilize energy from food/ metabolize protein, fats and carbohydrates ● Claim for specific population subgroups: - Additional amounts of Riboflavin are required during pregnancy and breast feeding when diet does not provide a sufficient daily intake	
Niacin (Vitamin B3)	● A factor in maintenance of good health	● Helps normal growth and development ● Helps the body in utilization of energy from food	
Pyridoxine (Vitamin B6)	● A factor in maintenance of good health	● Helps the body to metabolize proteins, fats and carbohydrates	

Cyanocobalamine (Vitamin B12)	• Helps in maintenance of good health	• Helps in the formation of red blood cell	
Folic Acid		• Helps in formation of red blood cell	• Helps prevent neural tube defects for women who are planning a pregnancy before conception and during 12 weeks of pregnancy at a dose of 400 mcg daily
Biotin	• Helps in maintenance of good health	• Helps to metabolize fats and carbohydrates	
Panthothenic Acid	• Helps in maintenance of good health	• Helps to metabolize fats and carbohydrates	
Calcium	• Helps in maintenance of good health	• Helps in the formation and maintenance of bones and teeth • Claim for specific subgroup: - Additional calcium is required for pregnant and lactating women, when diet does not provide a sufficient daily intake to help in proper bone	

		formation in developing baby	
Phosphorus	● Helps in maintenance of good health	● Helps in the formation and maintenance of bones and teeth	
Magnesium	● Helps in maintenance of good health	● Helps the body to metabolize carbohydrate	
Iron	● Helps in maintenance of good health	● Helps in the formation of red blood cell	
Iodine	● Helps in maintenance of good health	● Helps in the function of the thyroid glands	
Zinc	● A factor in maintenance of good health	● Helps to metabolize carbohydrates, fats and protein	
Copper	● A factor in maintenance of good health	● Helps in the formation of red blood cell	
Manganese		● Helps to metabolize carbohydrates and proteins	
Probiotics		● Helps to improve a beneficial intestinal microflora	

Notes:

1. *This list is not meant to be exhaustive and will be reviewed from time to time.*
2. *The Authority will nonetheless conduct a detailed evaluation of the evidence included in the report to ensure that the health claim is substantiated.*
3. *The Authority will be willing to consider review other than the listed above, if the standards of evidence are consistent with those of the Authority.*
4. *All references must be current*

Form: BMRR XIV-LS

APPLICATION FOR LISTING OF HEALTH SUPPLEMENTS

I/we ……hereby apply for listing of following Health Supplements manufactured by……
……..

Details of Health Supplement (*Use one application per product*)

Name of Product	**Pack size**	**Intended Use/Indication as printed on label and leaflet**	**Major ingredients**

Application fee has been deposited to the Royal Government of Bhutan
(Please submit a copy)

Declaration (please tick the boxes):

- ☐ I hereby declare that the documents submitted above/all information provided in the document above is true to my knowledge and will be liable for any consequences if any information provided is proved to be false or misleading.
- ☐ I declare that I have read the regulation and I am fully aware that my application may be rejected if I do not fulfill the conditions or contravenes the provision(s) of the act and regulations made there under.
- ☐ If my application is granted, I shall abide by the Medicines Act and Regulations and any other standards set by the Authority.

Signature of applicant

Name, address, contact no

Date……

16. Reference:

16.1 Annex I – ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Traditional Medicines and Health Supplements;

16.2 Annex II – ASEAN Guiding Principles for the Use of Additives and Excipients in Traditional Medicines and Health Supplements;

16.3 Annex III – ASEAN Guidelines on Limits of Contaminants for Traditional Medicines and Health Supplements;

16.4 Annex IV – ASEAN Guidelines for Minimizing the Risk of Transmission of Transmissible Spongiform Encephalopathies in Traditional Medicines and Health Supplements;

16.5 Annex V – ASEAN Guidelines on Stability and Shelf-Life of Traditional Medicines and Health Supplements;

16.6 Annex VI – ASEAN Guiding Principles on Safety Substantiation for Traditional Medicines and Health Supplements;

16.7 Annex VII – ASEAN Guidelines on Claims and Claims Substantiation for Traditional Medicines and Health Supplements;

16.8 Annex VIII – ASEAN Guidelines on Good Manufacturing Practice for Traditional Medicines and Health Supplements; and

16.9 Annex IX – ASEAN Guidelines on Labeling Requirements for Traditional Medicines and Health Supplements.

16.10 Food Safety and Standards (Health Supplements, nutraceuticals, food for special dietary use, food for special medical purpose, functional food and novel food), Regulations 2016, Food Safety & Standards Authority of India.

16.11 Health Supplements Guidelines, Revised August 2020, Health Sciences Authority, Singapore.

16.12 Malaysia Guideline on Registration of Health Supplements (Second Edition, Sept 2016. Revised July 2018)

We commit to provide consistent regulatory operations with risk based planning and continual improvement in compliance with the recognized standards to meet our consumers' satisfaction and confidence.

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