GUIDELINE FOR APPLICATION FOR IMPORTATION AND/OR SALE OF TRADITIONAL MEDICINE AND HEALTH SUPPLEMENT

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DEPARTMENT OF PHARMACEUTICAL SERVICES
MINISTRY OF HEALTH
BRUNEI DARUSSALAM

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GUIDELINE FOR APPLICATION FOR IMPORTATION AND/OR SALE OF TRADITIONAL MEDICINE AND HEALTH SUPPLEMENT

This guideline provides information for importation and/or sale of traditional medicine and health supplement in Brunei Darussalam. This guideline supersedes the 'Guidelines for Dealing with Traditional medicines and Health supplements'. The information provided in this guideline serves to supplement understanding and application for the Laws and Regulation as is not at any time meant to supersede or replace any of the legislation.

1. Legislation

Information on the current legislative control of medicines and related products may be found in the following legislation:

A. The Poisons Act (Cap.144) & The Poisons Rule.
B. Misuse of Drugs Act (Cap.27) & The Misuse of Drugs Regulation.
C. Medicines Order, 2007.

2. Definition

In this Guideline, unless the context otherwise requires:

A. i. "Traditional Medicine" means any product used in the practice of indigenous medicine, in which the medicine consist solely of one or more naturally occurring substances of a plant, animal or mineral, of parts thereof, in the unextracted or crude extract form, and a homeopathic medicine. (Medicines Order, 2007)

ii. "Homeopathic medicine" means any pharmaceutical dosage form used in the homeopathic therapeutic system in which diseases are treated by the use of minute amounts of such substances which are capable of producing in healthy persons symptoms similar to those of the disease being treated. (Medicines Order, 2007)

B. "Health supplement" means any product that is used to supplement a diet and to maintain, enhance and improve the healthy function of human body and contains one or more, or a combination of the following:

i. vitamins, minerals, amino acids, fatty acids, enzymes, probiotics and other bioactive substances;
ii. substances derived from natural sources, including animal, mineral and botanical materials in the forms of extracts, isolates, concentrates, metabolites;
iii. synthetic sources of ingredients mentioned in (i) and (ii).

Health supplement are presented in dosage forms and to be administered in small unit doses such as capsules, tablets, powder and liquids.

Health supplement shall <u>not</u> include any of the following:

a. Any product for use as conventional food or as the sole item of a meal or diet;
b. Any product that is defined otherwise in the legislation; and
c. Any injectable, sterile preparations or eye drops.
(Ref: ASEAN)

3. Safety & Quality Requirements

Currently, traditional medicine and health supplement do not require licence/ permit for their importation, manufacture and sale in Brunei Darussalam. The onus of the responsibility for the safety and quality of the said products, rests with the importers/ manufacturers/ wholesale dealers/ sellers. They must ensure that the products placed in the market comply with the safety and quality requirements provided in this Guideline.

Traditional medicine and health supplement shall:

i) not contain any other substances except those stated on the label;
ii) not contain any human part or substances derived from any part of the human body;
iii) not contain substances listed in the schedule of the Poisons Act (Cap. 144);
iv) not contain any substances listed in the first schedule of the Misuse of Drugs Act (Cap. 27);
v) not exceed the limits for microbial contamination and toxic heavy metals as specified in Section 4 of this guideline, where applicable;
vi) not contain any substances above the limits specified for Vitamins and Minerals shown in Section 5 of this guideline;
vii) not contain any substance as indicated in Section 6 of this guideline;
viii) not contain any active substance which is a chemically-defined isolated constituent of plants, animals or minerals, or a combination of any one or more of these;
ix) not contain any substances that may adversely affect the health of the person taking the product;
x) not make any claim to directly or indirectly to the list of diseases, disorders and its related conditions specified in Section 7(c) of this guideline;
xi) not contain any substances derived from any endangered species as stipulated under the Wildlife Protection Act (Cap. 102); and
xii) be of acceptable standards of quality in terms of product stability in the local climatic condition, have adequate shelf-life period, proper packaging and labeling; and are manufactured and/or assembled under proper condition or GMP certified premises.

4. Safety & Quality Specifications

The safety and quality levels are specified in the following tables. Certificate of Analysis (CoA) of the TMHS products containing the tests below shall be submitted as a supporting document.

1. Limit of Heavy Metals

Substance	Maximum limit
Lead	NMT 10.0 mg/kg or 10.0 mg/litre (10.0ppm)
Arsenic	NMT 5.0 mg/kg or 5.0 mg/litre (5.0ppm)
Mercury	NMT 0.5 g/kg or 0.5 mg/litre (0.5ppm)
Cadmium	NMT 0.3 mg/kg or 0.3 mg/litre (0.3ppm)

2. Limit for Microbial Contaminations

The limit used is based on British Pharmacopoeia (2013). Hence, the specifications may change as required according to the compendium requirements from time to time.

The list is not necessarily exhaustive and for a given preparation, it may be necessary to test for other micro-organisms depending on the nature of the starting materials and in the manufacturing process.

Test for Microbial Contamination

a) Microbiological Quality of Traditional medicine

Route of Administration	**Acceptable criteria for microbiological quality**		
	TAMC (CFU/g or CFU/ ml)	**TYMC (CFU/g or CFU/ ml)**	**Specified Microorganisms**
For Oral Use			
Traditional medicine containing materials of natural (animal, plant or mineral) origin for which antimicrobial pre- treatment is not feasible and for which the competent authority accepts TAMC of the material exceeding 103 CFU/gram or CFU/ml*	NMT 2×10^4	NMT 2×10^2	- NMT 10^2 CFU of bile- tolerant gram negative bacteria in 1g or 1ml - Absence of *Salmonella* in 10g or 10ml - Absence of *Escherichia coli* in 1g or 1ml - Absence of *Staphylococcus aureus* in 1g or 1ml
For External Use			
Oromucosal Gingival Cutaneous Nasal Auricular	NMT 2×10^2	NMT 2 x 10	- Absence of *Staphylococcus aureus* in 1g or 1ml - Absence of *Pseudomonas aeruginosa* in 1g or 1ml
Transdermal Patches (limits for one patch including adhesive layer and backing)	NMT 2×10^2	NMT 2 x 10	- Absence of *Staphylococcus aureus* in 1 patch - Absence of *Pseudomonas aeruginosa* in 1 patch

b) Microbiological Quality of Health Supplement (not applicable to products containing viable microorganisms as active ingredients)

Route of Administration	**Acceptable criteria for microbiological quality**		
	TAMC (CFU/g or CFU/ ml)	**TYMC (CFU/g or CFU/ ml)**	**Specified Microorganisms**
For Oral Use			
Health supplement products containing materials of natural (animal, plant or mineral) origin for which antimicrobial pre-treatment is not feasible and for which the competent authority accepts TAMC of the raw material exceeding 10^3 CFU/gram or CFU/ml	NMT 2×10^4	NMT 2×10^2	- NMT 10^2 CFU of bile- tolerant gram- negative bacteria in 1g or 1ml - Absence of *Salmonella* in 10g or 10ml - Absence of *Escherichia coli* in 1g or 1ml - Absence of *Staphylococcus aureus* in 1g or 1ml
Aqueous preparations	NMT 2×10^2	NMT 2 x 10	- Absence of *Escherichia coli* in 1g or 1ml
Non-aqueous preparations	NMT 2×10^3	NMT 2×10^2	- Absence of *Escherichia coli* in 1g or 1ml

5. Permissible Limits for Vitamins and Minerals in Health supplement

The following table specifies the limits for Vitamins and Minerals preparation which are allowed to be imported and/or sold as health supplement. Health supplement which contains the vitamins and minerals exceeding the maximum limit will not be accepted as health supplement and shall be classified as medicinal products.

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

*The conditions of use of Vitamin K are as follows:

Application:	For use in oral dosage form of multivitamin/mineral preparations for adults and not as a single ingredient health supplement
Vitamin K form:	Only Vitamin K1 and/or Vitamin K2
Cautionary statement:	"Consult a health care practitioner prior to use if you are on anticoagulant therapy/taking blood thinners such as warfarin"

Note: For products containing Niacin, the niacin content expressed as either nicotinic acid or nicotinamide must be declared in the application by including this information in the covering letter/separate letter.

6. Prohibited/Restricted Substances

a) All the ingredients listed in the Appendix I Negative List of Substances for Traditional Medicines and Appendix 2 Negative List of Substances for Health Supplements of the ANNEX I ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Traditional medicine and Health supplement are also **not allowed** as ingredients/ substances in traditional medicine and health supplement.

b) References may also be made to other established literatures.

7. Claims Guidelines

All claims made for traditional medicine and health supplement should:

- Be consistent with the definition of traditional medicine and health supplement
- Support the safe, beneficial and appropriate use of the products
- Maintain the level of traditional usage and/or scientific evidence which is proportionate to the type of claim
- Meet the dosing recommendations stated in the evidence or references for the claimed intended effects, unless otherwise justified
- Not be misleading or false
- Enable consumers to make an informed choice regarding products
- Be for health maintenance or treatment of disease in accordance with traditional principles and practice, where the product is a traditional medicine
- Be for health maintenance and promotion purpose, where the product is a health supplement
- Not be medicinal or therapeutic in nature, such as implied for treatment, cure or prevention of diseases, where the product is a health supplement
- Be substantiated by good quality evidence that is relevant to the claim

a) Types of traditional medicine claims

The 2 types of TM claims:

- Traditional Health Use Claims
- Traditional Treatment Claims

Scope and examples of the types of TM claims		
Type of TM claim	**Scope**	**Examples to illustrate the scope**
Traditional Health Use	Traditionally used for general health maintenance or enhancement	• Traditionally used to maintain health for people above 40 yrs old • Tonic traditionally used to restore energy and health in women after childbirth/puerperium • Tonic traditionally used to strengthen body by nourishing blood and invigorating vital energy
Traditional Treatment	Traditionally used to relieve or alleviate a symptom, or treat a disease or medical condition according to the principles of traditional medicine, with the exception of the prohibited diseases according to each Member State To prevent/stop/slow down the progress of a mild or self-limiting disease or medical condition, based on principles of traditional medicine	• A Traditional medicine for dizziness/vomiting during travel in car, boat and airplane • Traditionally used to prevent cold or flu • Traditionally used to relieve cold and sore throat • Traditionally used to treat stomachache • Traditionally used to treat constipation • A traditional medicine to relieve itchiness

b) Types of HS claims

The 2 types of HS claims:

- General or Nutritional Claims
- Functional Claims

Functional Claims shall be substantiated by the proportional degree of data from efficacy studies and relevant documentation.

The scope and examples of the types of HS claims		
Type of HS claim	**Scope**	**Examples to illustrate the scope**
General or Nutritional	For Nutritional Support and General Health Maintenance. Benefits derived from supplementation beyond a person's daily dietary intake.	• Supplements nutrition • Supports healthy growth and development • Nourishes the body • Relieves general tiredness, weakness • Helps to maintain good health
Functional	Relate to a positive contribution to health or to the improvement of a function or to modifying or preserving health in the context of the total diet on normal functions or biological activities of the body. Maintains or enhances structure or function of the body, excluding disease related claims. Supports health and to relieve/reduce/ lessen/ease minor body discomforts in some physiological processes (e.g. ageing, menopause, pregnancy).	• Maintains/Supports healthy joints • Maintains/Supports immunity • Maintains healthy liver function • Maintains/Supports alertness • Maintains/Supports mental performance • Promotes healthy skin • Helps to relieve post-menopausal discomforts • Aids in digestion to relieve indigestion • Bifidobacteria in product A helps to improve slow transit system in 14 days • Supports health in ageing • Supports health in menopause • Supports health in pregnancy

c) Prohibited Claims

Traditional medicine and health supplement must <u>not</u> be labelled, advertised or promoted to prevent, alleviate or cure any disease or disorders and its related conditions specified in the table below.

No.	Diseases or Disorders	No.	Diseases or Disorders
1.	Diseases or defects of the kidney	2.	Hernia or rupture
3.	Disease or defects of the heart	4.	Diseases of the eye
5.	Diabetes	6.	Hypertension
7.	Epilepsy or fits	8.	Mental disorder
9.	Paralysis	10.	Infertility
11.	Tuberculosis	12.	Frigidity
13.	Asthma	14.	Impairment of the sexual function or impotency
15.	Leprosy	16.	Venereal disease
17.	Cancer	18.	Sexual function
19.	Deafness	20.	Acquired Immunodeficiency Syndrome (AIDS)
21.	Drug addiction	22.	Conception and pregnancy

8. Labelling Guidelines

Labelling must be prominently and conspicuously displayed on the product at the point of sale. Where the size, shape or nature of the final product or package does not permit the full listing of labelling information, the use of inserts, leaflets and hang tags, in appropriate format, are allowed. However, the name of the product, the recommended dosage, the batch reference and relevant precautionary statements should be displayed on the final product or package.

The types of information to be provided on the label are shown below. They should be adequate and truthful. The information shall be in **English and/or Malay** and shall be printed in a clear and legible manner.

No.	Information to be provided
1.	Product name
2.	Dosage form
3.	Name and strength/quantities of the active ingredient(s)*
4.	Indication
5.	Recommended daily dosage
6.	Instructions on proper usage
7.	Pack size
8.	Batch number
9.	Expiry date or statement with similar meaning (e.g. “Use by”, “Use before”)
10.	Storage condition
11.	Name and address of manufacturer
12.	Name and address of product owner/ importer/ wholesaler where appropriate
13.	Precautionary label
14.	To declare the source of ingredients derived from animal origin (active and excipient) and gelatin (capsule shell)

*It is recommended that internationally accepted nomenclature be used for ingredient names. For example, the name of plants or animals from which the active ingredient is derived should be declared in scientific name followed by plant part and type of preparation where applicable. The use of the common name of the active ingredient is optional. For minerals, common or chemical names should be used.

9. Other Information

a) Please be reminded that the onus of responsibility to ensure the safety and quality of traditional medicine and health supplement product rests on the company responsible (importers, manufacturers, wholesale dealers and sellers).

b) Please be reminded that for every importation of TMHS must go through Brunei Darussalam National Single Window (BDNSW) for endorsement. To facilitate the importation, you are encouraged to submit the application for importation and/or sale of TMHS to the TMHS Unit prior to its importation.

c) This Guideline shall be updated or revised from time-to-time as other new legislation or regulation are implemented or as a current legislation or regulation are revised.

10. References

A. Medicines Order, 2007
B. Poison Act (Cap.144) & The Poisons Rule
C. Misuse of Drugs Act (Cap.27) & The Misuse of Drugs Regulation
D. ASEAN Annexes on Traditional medicines (TM) and Health supplements (HS)
    a. Annex I ASEAN Guiding Principles for Inclusion into or Exclusion from the Negative List of Substances for Traditional Medicines and Health Supplements
    b. Annex II ASEAN Guiding Principles for the Use of Additives and Excipients in Traditional Medicines and Health Supplements
    c. Annex III ASEAN Guidelines On Limits of Contaminants for Traditional Medicines and Health Supplements
    d. Annex IV ASEAN Guidelines for Minimising the Risk of Transmission of Transmissible Spongiform Encephalopathies in Traditional Medicines and Health Supplements
    e. Annex V ASEAN Guidelines On Stability Study and Shelf-Life of Traditional Medicines and Health Supplements
    f. Annex VI ASEAN Guiding Principles On Safety Substantiation of Traditional Medicines and Health Supplements
    g. Annex VII ASEAN Guidelines On Claims and Claims Substantiation for Traditional Medicines and Health Supplements
    h. Annex VIII ASEAN Guidelines on Good Manufacturing Practice for Traditional Medicines and Health Supplements
    i. Annex IX ASEAN Guidelines On Labeling Requirements for Traditional Medicines and Health Supplements
    j. Annex X ASEAN General Principles for Establishing Maximum Levels of Vitamins and Minerals In Health Supplements
E. British Pharmacopoeia (2013)

11. Application form and its related documents

The application form and its related documents can be requested via email from **tmhs.unit@moh.gov.bn** or via Ministry of Health website.

12. Application Submission

Completed application form can be submitted to:

Traditional Medicine and Health Supplement Unit (TMHS Unit)
Product Regulation Section
Department of Pharmaceutical Services
Second Floor, Spg 433,
Building of the Department of Pharmaceutical Services,
Kg Madaras, Rimba Highway,
Negara Brunei Darussalam

13. Contact Details

The TMHS Unit can be contacted by:

a) Telephone: 2393298 / 2393301 ext 225
b) Email: tmhs.unit@moh.gov.bn