Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Registration of Nutraceuticals

Guideline for Registration of Nutraceuticals is released under the authority of

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Maldives Food and Drug Authority
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SUMMARY OF CHANGES

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	01.03.2024	-	Creation of the document	Mohamed Fazeen, Senior Pharmacist
2	22.10.2023	7.1.1, Introduction	Specify applications are submitted and accepted through Dhirithi Portal, Rephrasing for clarification.	Mohamed Fazeen, Senior Pharmacist
3	03.09.2024	1.1, overall document	Addition of how a product is classified as a nutraceutical, Correction of the name of Technical Committee on Nutraceuticals (TCN) throughout the document, formatting	Mohamed Fazeen, Senior Pharmacist

Contents

ABBREVIATIONS AN DEFINITIONS

Nutraceutical	Nutraceutical is defined as a vitamin and supplement that provides the body with medical or health benefits, including the physiological changes, prevention of a disease and treatment of a disease with lower strength of active ingredients (below than the daily maximum recommended dose).
Technical Committee of Nutraceutical Approval	Assigned staff from the 03 divisions (Medicine and Therapeutic Goods Division (MTG), Food Control Division (FCD) and National health Laboratory (NHL) of Maldives Food and Drug Authority (MFDA)
Brand Name	A drug manufactured and sold by a manufacturer under a specific name or trademark is called brand name or trade name.
Generic Name	This is the shortened chemical name of the actual drug. Sometimes it is known as the international name of the drug.
Dosage Form	Dosage form is the way the final medicinal product is presented for usage.
Manufacturer	A company who manufactures medicines for trade use.
Medicine and Therapeutic Goods Division (MTG)	The medicine regulatory division of Maldives Food and Drug Authority.
Country of Origin	The country of origin is the country where the medicine was produced or manufactured.
Medicine and Therapeutic Goods Division (MTG)	The medicine regulatory division of Maldives Food and Drug Authority.
Medicine Importers	The register and licensed party to import the medicines by Maldives Food and Drug Authority.
Pharmacies	This is the registered retail medicine shops where they can store and sell medicines.
Prescription Only Medicine (POM)	This is a category of medicine which can be sold only for a valid prescription only.
Strength	The strength is the amount of drug in the dosage form or a unit of the dosage form
Ministry of health (MOH)	Ministry of Health, Government of Maldives is the apex body providing leadership and guidance to protect health and wellbeing of the citizens of Maldives. It promotes health through

	a high quality and comprehensive health care system which is effective, efficient, responsive, affordable, equitable and accessible to all in the country. It regulates and provides policy guidance in matters of health, setting norms and standards for service delivery and coordinate with other national and international stakeholders."
Maldives Food and drug authority (MFDA)	Competent Authority which is under the Ministry of health to regulate the Food and Medicines.
Good Manufacturing Practice (GMP)	**Good Manufacturing Practice** (GMP) is a system for ensuring that products are consistently produced and controlled according to quality standards. It is designed to minimize the risks involved in any pharmaceutical production that cannot be eliminated through testing the final product.
g	grams
mg	milligrams
mcg	milligrams
iu	International units
TCN	Technical Committee on Nutraceuticals

1 INTRODUCTION

Nutraceuticals are used extensively among all the age groups of the population. The market for dietary supplements and nutraceuticals taken to improve the health or well-being of the customer is enormous. However, they are not necessarily safe for everybody. Like regular drugs, supplements with active ingredients that provide a physiological effect are likely to also cause adverse effects in susceptible individuals. Therefore, more attention to adverse effects and potential interactions is needed in order to avoid serious medical outcomes.

For example, some dietary supplements can be beneficial as these products contain active ingredients — molecules that interact at receptors in our body and cause physiological changes. However, *because* they contain active ingredients, they can also cause unwanted effects, such as elevated blood pressure, racing or irregular heartbeat, headache, dizziness, or digestive symptoms.

Hence, though there is no specific clause in the regulation for Nutraceuticals we are required to establish a mechanism to ensure the safety and quality of the nutraceuticals imported and sold in the Maldives.

This guideline has been developed to guide the medicine importers to register the product prior to import.

1.1 Classifying as Nutraceuticals

Nutraceutical is defined as a vitamin and supplement that provides the body with medical or health benefits, including the physiological changes, prevention of a disease and treatment of a disease with lower strength of active ingredients less than the daily maximum recommended dose).

Additionally, the products containing vitamins and minerals with less than the daily recommended dose and if the product is to be used as per the advice of a doctor/Physician, also shall be considered as nutraceuticals.

If it does not have any therapeutic claim and if the strength is lower than the daily recommended dose, it shall be considered as a food supplement.

Moreover, the product can be classified as a nutraceutical of a food supplement based on the regulatory classification in the manufacturing country of the product.

2 PURPOSE

This guideline has been developed as a guidance on how to process with the registration of nutraceutical products for the importers, Pharmacies, staff of Medicine and Therapeutic Good Division (MTG) of Maldives Food and Drug Authority (MFDA) and the Officers who are involves in the process.

3 SCOPE

This guideline has been developed to guide the importers who are registered at the Maldives Food and Drug Authority in the preparation and submission of Nutraceutical registration in the form of application.

4 RESPONSIBILITY AND ACCOUNTABILITY

There are four (4) staff who are responsible and accountable for this process.

Staff	Responsibility and Accountability
Senior Public Health Regulation Unit (MTG)	▪ Check and verification of the submitted documents. ▪ If the submitted documents are acceptable, accept the application and arrange for submission fees. ▪ Rejection of application if documents are not acceptable or unable to verify. ▪ Evaluation of the application and submit to the TCN for Final Decision ▪ If the product is approved, arrange to receive the registration fees. ▪ Prepare and issue the registration certificate.
Senior Pharmacist Regulation Unit (MTG)	▪ Is to verify the evaluation report and the submitted documents prior to the approval by the Pharmaceutical Specialist. ▪ Check and verify the registration certificates ▪ Check and verify the Approved Nutraceutical List prior to it is published.
Pharmaceutical Specialist (MTG)	▪ Approve/ Reject based on the outcome of the
Technical Committee on Nutraceuticals (TCN)	▪ Opinion and recommendations on further process of the application once evaluated.
National Pharmaceutical Board	▪ Advice on approval/rejection of the product ▪ Is to sign the authorization of the registration certificates.

5 Guideline content

5.1.1 The guideline applies only for approved medicine importers to register nutraceuticals.

5.1.2 The applicant shall ensure that all the information given in Dhirithi Portal (www.Dhirithi.egov.mv) and supporting documents are true and valid at the time of submitting the application.

5.1.3 The applicants are responsible for determining that the claims made on their products are accurate and truthful and can be substantiated with good quality evidence. In addition, whether a claim is acceptable on an advertisement would require consideration of the advertisement and its context in its entirety.

5.1.4 The technical evaluation of the Nutraceutical product is done by the assigned staff Medicine and Therapeutic Goods Division and approved by the TCN. This teams consist of 05 members including the Director Pharmaceuticals, 01 staff from Medicine and Therapeutic Division, 02 Staff from Food Control Division of MFDA, 01 staff from National Health Laboratory.

6 Submission of Application

6.1.1 Any local party who is registered in MFDA as a medicine importer can submit the application for the interested brands of nutraceuticals to import through Dhirithi Portal (www.dhirithi.egov.mv)

6.1.2 All regulatory certificates must be notarized.

6.1.3 All the certificates should have a validity period of not less than 6 months at the time of submission. If validity period is less than six months at the time of submissions a commitment letter is required. However, registration certificate will be provided upon receiving of the renewed document.

6.1.4 When applying for multiple products, separate application is required for each product i.e., products containing the same ingredients but made to different specifications (in terms of strength/content of ingredient(s), dosage form, description, pack size etc.) or by a different manufacturer shall require separate applications for product registration.

6.1.5 If the expiry dates are not mentioned in the certificates, there should be an explanatory note or an official document stating the reason.

6.1.6 For further clarification please contact us through the hotline for MTG, 7200321.

7 General Requirement

7.1 In general, the following documents are required (All documents must be prepared in English language):

7.1.1 Company Profile: The company profile documents should include the detail of the following.

a. Complete and detailed address of the Manufacture including phone and fax number.
b. Brief introduction of the manufacture.
c. List of the product category manufactured
d. State whether the company is manufacturing under loan license or not. If so, include details.

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

a. Name/Brand name
b. Dosage Form
c. Product Composition
d. List of all ingredients in the dosage form and their amount on a per unit basis
e. Description of the organoleptic characteristics of the product; including size,
f. shape, superficial markings for identification purposes, color, odor, taste,
g. consistency, type of tablet or capsules etc.
h. Commercial presentation of packaging and pack size in terms of
i. quantity/weight/volume etc.
j. Intended use for the product with a description of how to use it.

7.1.3 Specifications of the finished product

7.1.3.1 Provide certificates of analysis for finished product.

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

a. Summary of the profile of the plant used including botanical name, genus, species, subspecies, plant parts used, whether cultivated or wild, harvesting practices and treatment to obtain raw materials.
b. Data to demonstrate the safety of each herbal ingredient in human beings e.g. through bibliographic or scientific studies

c. Description of the physiological functions of the herbal ingredient(s)/supplement to the intended use

7.1.4 Labelling Requirements

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

7.1.4.2 The label information should be English.

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

a. Product Name

b. Dosage Form

c. Name and Strength of Active ingredient

d. Batch or Lot Number

e. Manufacturing and expiry date or Expiry date only

f. Directions of use

g. Indication or Intended use

h. Storage condition

i. Name and address of manufacturer

j. Country of Origin

k. Pack Size

l. Warning/precaution if any

7.1.5 Proof of the manufacturing site for the product is GMP compliant (Valid WHO type GMP certificate). or any other documentation which can ensure that the facility is permitted to manufacture the nutraceuticals from a regulatory or international accredited body

7.1.6 The following information shall be included in the document GMP certificate

a. Bear the name of the firm, the date of certification and identity of the issuing authority.
b. Be valid and should have remaining validity of at least 06 months during the time of submission OR
c. If the certificate is nearing its expiration, evidence of application or under process letter for renewal of same issued by the licensing authority must be submitted along with the certificate.
d. If GMP certificate is unavailable, the local agent or manufacturer of the product should submit a commitment letter.

7.1.7 Brief profile of manufacturer(s), range of products manufactured and marketed in country

7.1.8 Technical documents for raw materials

a. Details of raw material source

b. Proof of quality and purity

7.1.9 Following information about manufacturing process shall be submitted:

a. Flow diagram and the brief description of the process

7.1.10 Certificate of Analysis (CoA) of finished product

7.1.10.1 The CoA of the Finished Product should include the results of all the requirements and test methods stated in the technical/quality specification of the finished product. The Certificate, validated and certified should:

a. Be on a letterhead or other copy that adequately identifies the manufacturer of the product.
b. Be dated with the date of analyses and signed by an authorized person against the name.
c. State the specifications and methods against which and by which the tests are performed.
d. Give all tests and analyses that involve measurement as the actual numerical results and not descriptions like "complies" or "pass".
e. Declare acceptable in case of such document being computer generated.

Note: COA from the applied products manufacturer`s laboratory shall not be accepted.

8 Regulatory situation

8.1.1 Evidence supporting the product is registered in the origin/ or Free sale certificate/ or exported to country other than the origin. (Should have the validity of 06 months at the time of submission).

8.1.2 Free sale certificate of the product

a. It should contain the following:

- Brand Name
- Generic Name or INN name
- Dosage form and strength
- Complete name and address of the manufacturer

8.1.3 Product samples:

8.1.3.1 Samples of finished product submitted for registration shall be taken at random from an actual product batch.

8.1.3.2 Samples submitted must be intact, it must be in final commercial pack with original labels, and package inserts.

8.1.3.3 For the products with various ingredients (such as vitamins) may not have all the ingredient mentioned in the outer pack. For such cases label has to be fixed as per the recommendation of MFDA.

8.1.3.4 Product samples submitted must have a remaining shelf-life of at least half of its shelf-life.

8.1.3.5 If the product is without an out carton, the inner label should bare all the information that is required and should tally with the documents submitted.

8.1.3.6 The color of the labels should be differentiated between strengths of products. The label must be made from good quality material.

9 Processing of Application

9.1.1 Once received the dossier from the Dhirithi Portal documents will be checked and verified within 15 (fifteen) working days.

9.1.2 If all the documents are complete and acceptable, it will be notified from Dhirithi Portal.

9.1.3 In any circumstances if the dossier is rejected, the submitted samples will be non-refundable.

9.1.4 The submitted samples will be discarded after 3 months from the date of rejection.

9.1.5 An application for registration will be rejected if the applicant fails to submit all the required documents and complete the registration formalities.

10 Evaluation of the application

10.1.1 Once the application is accepted and the submission fees are paid the evaluation process will be started and completed within 30 (thirty) working days.

10.1.2 The assigned staff of the Regulation Unit of Medicine and Therapeutic Goods Division do the technical evaluation of the medicinal product dossier.

10.1.3 The evaluation summary will be checked and verified by the section head.

10.1.4 Once it is checked and verified, the division head will approved/reject the application based on the outcome of the evaluation.

11 Regulatory Decision

11.1.1 Once the evaluation is completed, it will be submitted to the TCN for their comments and recommendations.

11.1.2 Upon receiving the recommendation and comments from the TCN it will be submitted to the National Pharmaceutical Board for their opinion for approval/rejection.

11.1.3 The decision will be accordingly communicated to the applicant within 30 (thirty) days after the evaluation has been completed.

12 Approval of Product

12.1.1 If the product is approved, it will be notified to the local agent via Dhirithi portal 5 working days.

12.1.2 The registration fees will be request via Bandeyri portal 5 working days.

12.1.3 Once the registration fees are paid the certificate will be issued

13 Rejection of a Product

13.1.1 If the product is rejected from the TCN, it will be informed to the Local agent via Dhirithi portal within 5 (five) working days.

14 Issuing Permit

14.1.1 The certificate for registered product will be issued in the specified format.

14.1.2 The registration certificate shall be issued within 10 (ten) working days from the date of registration fees are paid, unless otherwise a longer period is required, in which case, the party will be informed.

14.1.3 The validity of the permit is 5 (five) years from the date of issued.

15 Approved Nutraceutical List

15.1.1 Approved Nutraceutical List (ANL) is the approved list of Nutraceuticals which can be imported and sold within the country. This list is updated on the 10th of every month and uploaded to the Ministry of Health`s website (www.health.gov.mv).

15.1.2 Once the product is approved by the TCN it will be added to the list next month.

15.1.3 Upon approval of the product, the applicant will be asked to settle the registration fees (300/- MVR) via dhirithi portal.

15.1.4 Once the payment is settled, the product will be added to the Approved Nutraceutical List and the list will be published.

16 Re-registration

16.1.1 If the client wishes to continue with the product, it is encouraged to apply for the re-registration prior to the 45 days of expiration of the existing permit.

16.1.2 In general, the following documents are required (All documents must be prepared in English language):

a. Company Profile: The company profile documents should include the details of the following.

b. Complete and detailed address of the Manufacture including phone and fax number.

c. Good Manufacturing Practice License

d. Previous Permit of MFDA

e. Samples :

- Tablets/Capsules: 60 Nos
- Syrup/ Liquid: 03 Bottles
- Powder: 1 Jar/ sachets

17 Responsibility of Marketing Authorization Holder

17.1.1 Take responsibility to maintain the traceability and recall of the product from all wholesalers and medicine outlets in case of issues safety, quality and/ or alert on the product.

17.1.2 Provide information on any changes to the product formulation including label and information submitted for registration.

17.1.3 Comply with existing Laws, Regulations and Rules.

18 Legal basis and references

a. Medicine Regulation R-46 (2014)

b. Medicine Regulation Amendment R-49 (2016)

c. Health service act (29/2015)

19 References

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3. Dr. Tomislav Meštrović, P. (2022). Nutraceutical Regulation. Retrieved 26 February 2022, from https://www.news-medical.net/health/Nutraceutical-Regulation.aspx

Annex 1: Reference Guide: Daily Values for Nutrients

Nutrient	Current Daily Value
Added sugars	50g
Biotin	30mcg
Calcium	1300mg
Chloride	2300mg
Choline	550mg
Cholesterol	300mg
Chromium	35mcg
Copper	0.9mg
Dietary Fiber	28g
Fat	78g
Folate/Folic Acid	400mcg DFE
Iodine	150mcg
Iron	18mg
Magnesium	420mg
Manganese	2.3mg
Molybdenum	45mcg
Niacin	16mg NE
Pantothenic Acid	5mg
Phosphorus	1250mg
Potassium	4700mg
Protein	50g
Riboflavin	1.3mg
Saturated fat	20g
Selenium	55mcg
Sodium	2300mg
Thiamin	1.2mg

Nutrient	Current Daily Value
Total carbohydrate	275g
Vitamin A	900mcg RAE
Vitamin B6	1.7mg
Vitamin B12	2.4mcg
Vitamin C	90mg
Vitamin D	20mcg
Vitamin E	15mg alpha-tocopherol
Vitamin K	120mcg
Zinc	11mg