Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Registration of Nutraceuticals

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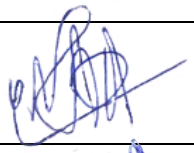
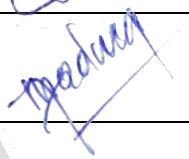
Approved By	Aishath Mohamed, Deputy Director General, Pharmaceuticals	
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

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
4	29.09.2025	Overall document	Formatting changes	Mohamed Fazeen, Director, Pharmaceuticals
5	15.12.2025	Overall document	Changes to definitions, Addition of procedure and flowchart for distinguishing between medicines, nutraceuticals, food supplements	Mohamed Fazeen, Director, Pharmaceuticals Mariyam Laisa, Asst. Medicine Regulatory Officer

Contents

ABBREVIATIONS AN DEFINITIONS

Borderline products	A borderline product is a product that cannot be clearly classified into a single regulatory category because its characteristics overlap with two or more defined product types (such as medicines, medical devices, food supplements, cosmetics, biocides, etc.). Because of this overlap, it is unclear which regulatory framework applies until a competent authority assesses its intended use, claims, and mode of action.
Nutraceutical	Nutraceuticals are products derived from food or food constituents that contain one or more bioactive substances and are presented in a concentrated or processed form (such as capsules, tablets, powders, or liquids), intended to supplement the normal diet and support or maintain normal physiological functions and overall health, **without making claims for the diagnosis, treatment, cure, or prevention of disease**.
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 increasingly used across all age groups for maintaining health and wellness. The global market for dietary supplements and nutraceutical products is rapidly expanding, driven by consumer demand for products that support health, vitality, and disease prevention.

While many nutraceuticals are beneficial, they are not inherently safe for all individuals. The mode of action of nutraceutical is mainly Functional, sometimes mildly pharmacological. These products may cause undesired effects in susceptible populations or interact with medicines. Therefore, a robust regulatory framework is essential to ensure the safety, quality, and efficacy of these products in the Maldives.

Currently Nutraceuticals are regulated under the mandate of the Maldives Food and Drug Authority (MFDA), a mechanism has been established to evaluate, register, and monitor nutraceutical products imported or sold in the country.

This guideline provides practical direction for importers, evaluators, and relevant stakeholders on the registration process for nutraceuticals before importation.

Definition:

- Nutraceuticals are food-derived products formulated to provide medical or health benefits beyond basic nutrition, including supporting physiological functions, reducing disease risk, or enhancing overall well-being.
- Nutraceuticals may contain:
    1. Vitamins, minerals, amino acids, or bioactive compounds.
    2. Extracts or concentrates of natural substances.
    3. Ingredients in dosages that are below the pharmacological range used in medicines.
    4. They are not intended to diagnose, treat, cure, or prevent disease, and must not bear therapeutic claims.
- A food supplement is a product intended to supplement the normal diet and provide nutrients such as vitamins, minerals, amino acids, or other substances that have a nutritional or physiological effect. Food supplements cannot claim to treat or prevent disease.

2 PURPOSE

The purpose of this guideline is to:

- Provide clear instructions on the requirements, procedures, and documentation needed for registration of nutraceutical products.
- Ensure safety, quality, and proper labeling of nutraceuticals available in the Maldives market.
- Assist importers, pharmacies, and MFDA staff involved in evaluation, decision-making, and monitoring processes.
- Promote consistency, transparency, and accountability in regulatory decisions related to nutraceuticals.

3 SCOPE

This guideline applies to:

- All importers registered with MFDA who intend to import nutraceutical products into the Maldives.
- MFDA staff are involved in product evaluation, approval, and monitoring.
- Products are categorized as nutraceuticals or food supplements based on their composition, claims, and intended use.

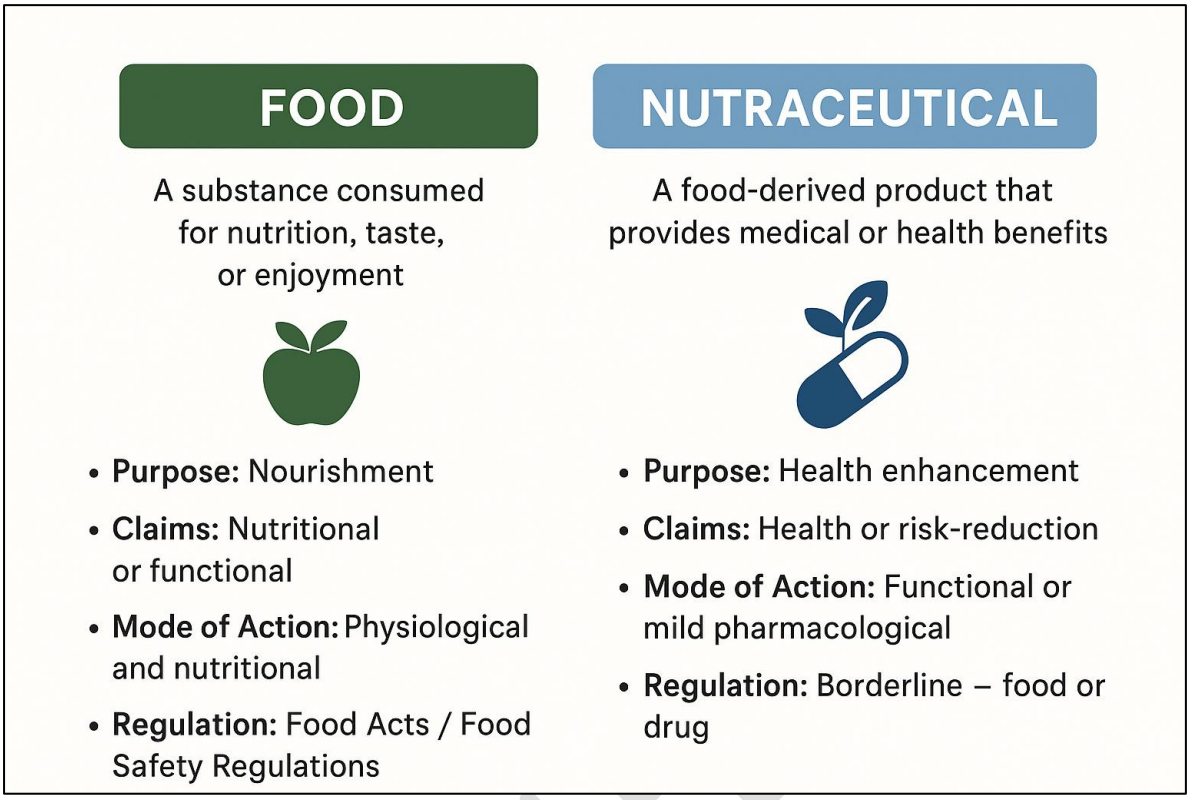
This guideline does not apply to:

- Licensed pharmaceuticals or therapeutic products regulated under the Medicines Regulation (R-46/2014).
- Conventional foods or beverages are marketed solely for nutrition without functional or health claims.

4 RESPONSIBILITY AND ACCOUNTABILITY

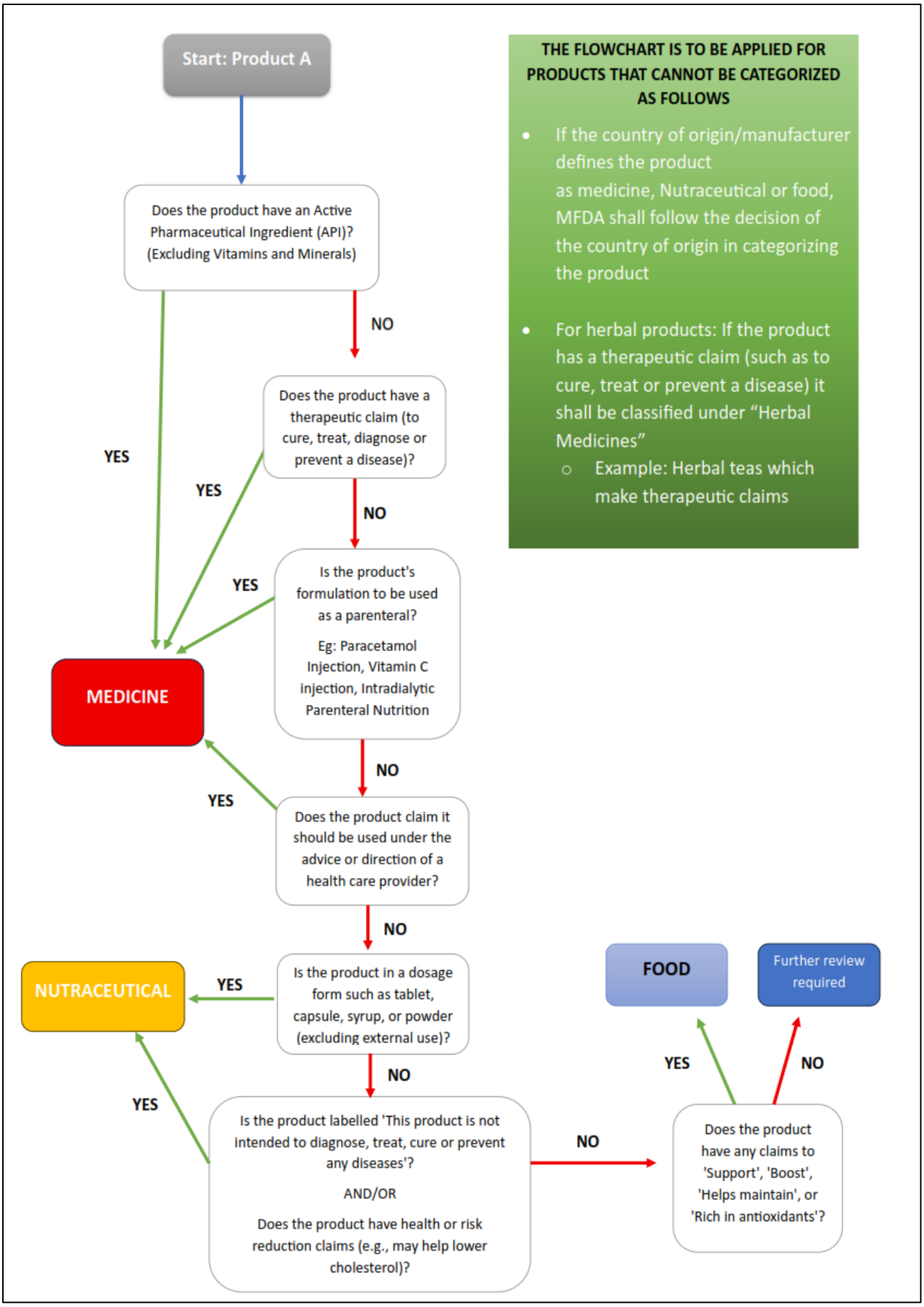
Staff	Responsibility and Accountability
Medicine Regulatory Officer	▪ Evaluate which category the product is and if it falls under nutraceuticals proceed as below. ▪ Check and verification of the submitted documents. ▪ If the submitted documents are acceptable, accept the application and arrange for submission fees. ▪ Rejection of application if documents are not acceptable or unable to verify.

	▪ Arrange the meeting for TCN and NPB. ▪ Evaluation of the application and submit it to the TCN for Final Decision ▪ If the product is approved, arrange to receive the registration fees. ▪ Prepare and issue the registration certificate. ▪ Update and publication of the Approved Nutraceutical List
Director Pharmaceuticals (MTG)	▪ Further verify if the product falls under nutraceuticals ▪ Is to verify the evaluation report and the submitted documents prior to the approval by the Director Pharmaceuticals. ▪ Approved the products for the submission to TCN and NPB. ▪ Check and verify the registration certificates. ▪ Check and verify the Approved Nutraceutical List prior to it is publication. ▪ Approve/Reject the products from the portal based on the final decision.
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
Deputy Director General	▪ Approve/ Reject based on the outcome of the TCN and NPB
Director General	▪ Authorize the final decision.



To avoid further confusion, all herbal products with therapeutic claims such as treatment, cure or prevent a disease or condition are categorized as herbal medicines and it will be regulated as per the regulation of herbal medicine. This includes various herbal teas with therapeutic claims, Herbal oral formulations with therapeutic claims etc.

5 Product Categorization


Start: Product A
Does the product have an Active Pharmaceutical Ingredient (API)? (Excluding Vitamins and Minerals)
NO
YES
Does the product have a therapeutic claim (to cure, treat, diagnose or prevent a disease)?
YES
NO
Is the product's formulation to be used as a parenteral?
Eg: Paracetamol Injection, Vitamin C injection, Intradialytic Parenteral Nutrition
YES
MEDICINE
NO
YES
Does the product claim it should be used under the advice or direction of a health care provider?
NO
NUTRACEUTICAL
YES
Is the product in a dosage form such as tablet, capsule, syrup, or powder (excluding external use)?
NO
YES
Is the product labelled 'This product is not intended to diagnose, treat, cure or prevent any diseases'?
AND/OR
Does the product have health or risk reduction claims (e.g., may help lower cholesterol)?
NO
Does the product have any claims to 'Support', 'Boost', 'Helps maintain', or 'Rich in antioxidants'?
YES
NO
FOOD
Further review required
THE FLOWCHART IS TO BE APPLIED FOR PRODUCTS THAT CANNOT BE CATEGORIZED AS FOLLOWS
If the country of origin/manufacturer defines the product as medicine, Nutraceutical or food, MFDA shall follow the decision of the country of origin in categorizing the product
For herbal products: If the product has a therapeutic claim (such as to cure, treat or prevent a disease) it shall be classified under "Herbal Medicines"
Example: Herbal teas which make therapeutic claims

5.1 The above Flowchart for Product Categorization outlines how to determine whether a product should be classified as a medicine, nutraceutical, herbal medicine, or food by the MFDA.

5.2 The Purpose of this flowchart is to provide a systematic decision-making pathway for categorizing products as medicine, nutraceutical or food based on their composition, claims, labeling, and intended use. It ensures consistent and transparent classification aligned with MFDA and international regulatory principles.

5.3 In addition, it is very important to consider that products must be properly labelled to efficiently categorize it.

Step 1: Check Classification in the Country of Origin

- If the Regulatory Authority of the country of origin or manufacturer has already classified the product as a medicine, nutraceutical, or food, MFDA will follow the same classification for consistency, unless there is clear evidence that the product is marketed differently.
- **However, any product presented in any parenteral dosage forms will be classified as medicine.**

Step 2: Identify Active Pharmaceutical Ingredients (APIs)

- Question: Does the product contain an Active Pharmaceutical Ingredient (API) (excluding basic vitamins and minerals)?

→ If YES: The product is classified as a medicine.

- Additionally, any chemical intended for use in the treatment, prevention, or diagnosis of disease is considered a medicinal product.
- Examples: Products containing paracetamol, ibuprofen, or antibiotics are medicines.
- **Multivitamins and mineral supplements without APIs are not categorized as medicines.**

➜ If NO: Proceed to the next step.

Step 3: Evaluate Therapeutic Claims

- Question: Does the product make therapeutic claims, such as cure, treat, diagnose, or prevent a disease or medical condition?

➜ If YES: The product is classified as a medicine.

- For herbal-based products, classify as Herbal/Alternative Medicine. Example: Herbal teas claiming to "treat cough" or "control diabetes" are Herbal Medicines.
- For non-herbal products, classify as Medicine. Example: Paracetamol relieves pain and fever
- All products formulated for parenteral administration are classified as medicinal products, such as paracetamol injection, ascorbic acid (vitamin C) injection, and intradialytic parenteral nutrition etc.

➜ If NO: Proceed to the next step.

Step 4: Check for Healthcare Professional Supervision

Question: Is the product labeled or promoted for use under the advice or supervision of a healthcare professional?

➜ If YES: Classify as a medicine.

This applies to products labeled "Take only under medical supervision" or "Use as advised by your doctor."

➜ If NO: Proceed to Step 5.

Step 5: Determine Dosage Form

Question: Is the product in a dosage form such as tablet, capsule, syrup, or powder (excluding external use)?

➜ If YES: The product is categorized as a Nutraceutical.

➜ If NO: Proceed to Step 6.

Step 6: Assess Labeling and Claims

Question: Does the product bear the disclaimer:

"This product is not intended to diagnose, treat, cure, or prevent any disease"?

➜ If YES or ➜ If NO Continue with the next step

Step 7: Assess Health or Risk Reduction Claims

Question: Is the product food derived? and have health or risk reduction claims (e.g., may help lower cholesterol)?

➜ If YES: Classify as a Nutraceutical.

➜ If NO: proceed to next step

Question: Does the product claim to "support," "boost," "help maintain," or is "rich in antioxidants"?

➜ If YES: Classify as food

➜ If NO: Proceed to Step 8

Step 8 : Borderline or Unclear Cases

If the product does not fit clearly into any category, or if conflicting evidence exists between formulation, labeling, and intended use:

➜ Refer to the Borderline Product Committee for further review and classification.

In summary:

1. Medicine: Contains an API; makes therapeutic claims; or requires medical supervision. Example: Paracetamol tablets.
   All products formulated for parenteral administration are classified as medicinal products, such as paracetamol injection, ascorbic acid (vitamin C) injection, and intradialytic parenteral nutrition etc.

Medicines are regulated under the Guideline for Product Registration Including Emergency Use Approval (MTG/RE-RP/GLN-TE-001).

2. Herbal Medicine: Plant-based with therapeutic claims (treats, cures, prevents). Example: Herbal tea "for cough relief" etc.

Herbal products are regulated under the Guideline for Registration of Herbal, Alternative/Dhivehi Beys (MTG/RE-MD/GLN-TE 005).

3. Nutraceutical: Food-derived products in dosage forms (such as capsules, tablets, sachet, oral powders, or liquids) with health benefits or functional claims ("supports immunity").
   Example Omega-3 capsules, Melatonin Tablets etc.

Nutraceuticals are regulated under the Guideline for Registration of Nutraceuticals (MTG/RE-NC/GLN-TE 011).

4. Food: Intended for normal nutrition, no health or therapeutic claims. Example Juice, milk, cereals.

Food Products are regulated under Guidelines on Issuance of Health Clearance to Food Supplements Imported to Maldives MFDA-FCD GL 2-2020 (Rev 04 - October 2021)

6 General Requirements for Application

6.1 Eligibility

6.1.1 This guideline applies exclusively to approved medicine importers registered with the Maldives Food and Drug Authority (MFDA) under the *Medicines Regulation (R-46/2014)*, who intend to register nutraceutical products for importation and sale in the Maldives.

6.2 Accuracy and Validity of Information

6.2.1 The applicant shall ensure that all information entered into the Dhirithi Portal (www.dhirithi.egov.mv) and all supporting documentation submitted with the application are complete, accurate, and valid at the time of submission.
Providing false, misleading, or outdated information may result in rejection, suspension, or revocation of product registration.

6.3 Responsibility for Product Claims

6.3.1 Applicants are fully responsible for ensuring that all claims made on product labels, packaging, or advertisements are:

- Accurate and truthful,
- Scientifically substantiated by good quality evidence, and
- Consistent with the definition and scope of nutraceutical products.

6.3.2 The acceptability of a claim will depend on its wording, context, and presentation within the entire advertisement or promotional material.
Claims implying therapeutic, curative, or disease prevention effects are not permitted under this guideline and will result in rejection of the product.

7 Technical Evaluation and Approval Process

7.1 The technical evaluation of nutraceutical products shall be carried out by the assigned evaluation team under the Medicine and Therapeutic Goods Division (MTG) and reviewed by the Technical Committee on Nutraceuticals (TCN) for final approval. The Technical Committee on Nutraceuticals (TCN) comprises five (5) members as follows:

1. Director of Pharmaceuticals
2. One (1) staff member from the Medicine and Therapeutic Goods Division (MTG)
3. Two (2) staff members from the Food Control Division (FCD) of MFDA
4. One (1) staff member from the National Health Laboratory (NHL)

"The Chairperson will be chosen based on the availability of members on the date of the meeting. A staff member of the MTG will not be eligible to serve as Chairperson."

7.2 The committee evaluates the composition, claims, labeling, and safety of each product to ensure compliance with MFDA standards prior to granting registration approval

8 Submission of Application

8.1 Any registered medicine importer who holds a valid medicine import license issued by the the Maldives Food and Drug Authority (MFDA) is eligible to apply for the registration of nutraceutical products.

8.2 Applications must be submitted electronically through the Dhirithi Portal at www.dhirithi.egov.mv. Each applicant may apply for one or more brands of nutraceuticals intended for import and distribution in the Maldives, in accordance with this guideline.

8.3 Certification and Notarization Requirements

8.3.1 All regulatory certificates and supporting documents (such as GMP, Product Registration Certificates, or Manufacturing License) must be:

- Issued by a recognized competent authority from the country of manufacture, and
- Properly notarized to verify authenticity.

8.3.2 Unsigned, expired, or unverified documents will not be accepted for processing.

8.4 Certificate Validity

8.4.1 All certificates submitted must have a minimum validity period of six (6) months from the date of application submission.

8.5 Exception for GMP Certificates

8.5.1 If the Good Manufacturing Practice (GMP) certificate is valid for less than six (6) months but not less than three (3) months at the time of submission, the application dossier may still be accepted and evaluated. However:

- The registration certificate will not be issued until the renewed GMP certificate is submitted.
- If the importer fails to provide the renewed GMP certificate within six (6) months, the application will be rejected and the process closed.

8.5.2 This provision ensures flexibility while maintaining compliance with MFDA's quality assurance standards.

8.6 Other considerations for application submission

8.6.1 Separate Applications for Each Product shall be submitted

8.6.2 A separate application must be submitted for each individual product, even if products share the same active ingredients but differ in:

- Strength or concentration of ingredients
- Dosage form or formulation (e.g., tablet, capsule, syrup)
- Physical description or packaging
- Pack size
- Manufacturer

8.6.3 Each variation constitutes a distinct product requiring independent evaluation and registration.

8.6.4 Certificates Without Expiry Dates: If any submitted certificate does not specify an expiry or validity date, the applicant must provide:

- An official explanatory notes from the issuing authority, or
- A supporting document confirming that such certificates do not carry validity dates under the authority's standard practice.

8.6.5 Failure to provide this documentation may result in delays or rejection of the application.

8.6.6 Inquiries and Clarifications: For any clarification or assistance regarding application submission, document requirements, or system-related issues, applicants may contact the Medicine and Therapeutic Goods (MTG) Division through the MFDA hotline: 📞 7200321

9 Submission Requirements

9.1 Required Documentation

9.1.1 In general, the following documents are required to accompany every application for nutraceutical registration. All documents must be submitted in English language. Documents originally issued in another language must be accompanied by a certified English translation.

9.2 Company Profile

9.2.1 A complete company profile of the manufacturer must be submitted, containing the following details:

1. Full and detailed address of the manufacturing facility, including telephone, fax, and email contact information.
2. A brief introduction of the manufacturer, including history, ownership, and manufacturing capabilities.
3. A list of product categories currently manufactured at the site (e.g., nutraceuticals, food supplements, herbal preparations).
4. Provide a brief profile of the manufacturer(s), including:
5. Range of products manufactured and marketed both locally and internationally.
6. Key details about manufacturing capacity, quality systems, and market reputation.

7. Applicants must provide proof that the manufacturing site complies with Good Manufacturing Practice (GMP) standards. Acceptable evidence includes:
    - A valid WHO-type GMP Certificate, or
    - Other official documentation issued by a recognized regulatory authority or internationally accredited certification body, confirming that the facility is authorized to manufacture nutraceuticals.

8. The GMP certificate must clearly state the name of the manufacturing firm, date of certification, and name of the issuing authority.
9. A statement indicating whether the company manufactures under its own license or under a loan license agreement.

    - If operating under a loan license, provide complete details of the licensing arrangement and name of the licensed facility.

9.3 Product Profile

9.3.1 A detailed product profile must be submitted for each nutraceutical product. The information should include:

1. Product name / Brand name
2. Dosage form (e.g., tablet, capsule, syrup, powder)
3. Complete composition, listing all ingredients per unit dose (e.g., per capsule, per 10 mL, or per sachet)
4. Quantitative formulation, indicating the amount of each active and inactive ingredient
5. Organoleptic description (physical characteristics), including:
    - Size, shape, color, taste, odor, consistency, and distinguishing markings for identification
6. Commercial presentation, including packaging type and pack sizes (weight, quantity, or volume)
7. Intended use and directions for use, clearly describing the purpose, dosage, and method of consumption.

9.4 Specifications and Quality Standards of the Finished Product

9.4.1 Applicants must submit certified specifications and Certificate of Analysis (CoA) for the finished product, including:

- Results of all quality control tests performed on the product.
- Specifications must align with the declared formulation and relevant pharmacopoeia or in-house standards.

9.5 Additional Requirements for Products Containing Herbal Ingredients

9.5.1 For nutritional supplements containing herbal components, without any therapeutic claims, the following additional information is required:

a. A profile summary of the plant(s) used, including:

- Botanical name, genus, species, and subspecies
- Part(s) of the plant used (leaf, root, bark, etc.)
- Source (cultivated or wild-harvested) and details of harvesting and post-harvest processing

b. Safety data for each herbal ingredient, supported by bibliographic references or published scientific evidence demonstrating safety in humans.

c. A description of the physiological or functional role of each herbal ingredient relevant to the intended use of the product.

- Toxicological analysis report of the finished product
- Microbiological analysis report of the finished product

10 Labelling Requirements

10.1 General Principles

10.1.1 Labels must not contain any statement, design, or representation that is false, misleading, or deceptive, or that could create a mistaken impression about nature, composition, or function of the product.

10.2 Language

10.2.1 All label information must be provided in English. Additional languages may be included, provided that the English text remains clear and legible.

10.3 Mandatory Label Information

10.3.1 Each product label must display the following minimum information:

a. Product name

b. Dosage form

c. Name and strength of active ingredient(s)

d. Batch or lot number

e. Manufacturing and expiry date (or expiry date only, if appropriate)

f. Directions for use

g. Indication or intended use

h. Storage conditions

i. Name and address of the manufacturer

j. Country of origin

k. Pack size (quantity, weight, or volume)

l. Any applicable warnings or precautions

Note: Claims implying therapeutic, curative, or disease prevention effects are strictly prohibited on labels of nutraceutical products.

11 Raw Material Documentation

Submit technical details on all raw materials used in the formulation, including:

1. Source and supplier information
2. Certificates of quality and purity issued by the manufacturer or supplier

3. Evidence that all raw materials comply with food-grade or pharmaceutical-grade standards, as applicable

12 Manufacturing Process Information

Provide a concise but clear description of the manufacturing process, including:

- A flow diagram outlining key production steps.
- A brief narrative explaining the process, controls, and critical parameters.
  This information helps MFDA verify product consistency and quality assurance practices.

12.1 Certificate of Analysis (CoA) for Finished Product

12.1.1 Requirements

A Certificate of Analysis for the finished product must include:

a. Results of all analytical tests and quality parameters as stated in the product specification.
b. The CoA must be issued on the manufacturer's official letterhead and clearly identify the manufacturer.
c. The document must be dated and signed by an authorized quality control representative.
d. Specifications and methods used for testing must be clearly indicated.
e. All measurable results must be expressed as numerical values rather than general terms such as "complies" or "passes.
f. Computer-generated CoAs are acceptable if properly validated and certified.

MFDA may, at its discretion, require a third-party Certificate of Analysis to verify product quality or authenticity.

13 Regulatory Situation

13.1 Documentation Related to Regulatory Status

13.1.1 Proof of Registration

- A Certificate of Registration: Evidence demonstrating the regulatory status of the product in the country of origin.

- The Registration certificate must contain the following minimum information:
- Brand name / Trade name
- Generic or INN name (International Non-proprietary Name), where applicable
- Dosage form and strength
- Full name and address of the manufacturer
- Country of Origin

All certificates must be valid for a minimum of six (6) months at the time of submission

14 Product Samples

14.1 Applicants are required to submit the product samples to the MFDA for all new products in the quantities described below for each product. However, MFDA can request more quantities if required for analysis or as notified from time to time for various dosage forms based on the tests available.

14.2 These represent the minimum required quantities of samples that must be submitted for evaluation. Each sample must be provided along with its complete outer packaging, such as the carton, box, or any external cover, to ensure proper verification of labeling, artwork, and packaging information.

Type	Description	Quantity
Liquid dosage forms	These include solutions, syrups, elixirs, suspensions, emulsions etc.,	02 units shall be submitted. (e.g. 02 bottles of liquids.)
Solid dosage forms	These include tablets, capsules, , lozenges, etc.	20 units shall be submitted (e.g. 20 tablets, 20 capsules).

14.3 Request for sample import shall be applied online through Dhirithi portal. MFDA considers requests for grant approval within 10 working days. Samples shall only be imported once sample authorization approval has been issued.

14.4 All imported samples (full quantity imported) shall be handed over to MFDA once it is cleared from the ports and these samples shall be handed over to the product registration unit. The Sample submission sheet. (Annex VII) shall be submitted via e mail (medicine.registration@health.gov.mv) before handing over the samples.

14.5 Sample Submission:

1. Samples must be handed over to MFDA once dossier application is submitted through the Dhirithi Portal.

2. All product samples must be submitted to the Maldives Food and Drug Authority (MFDA) **within five (05) working days** from the date of **customs or port clearance**. Sample submissions will be accepted **only on Mondays and Thursdays**, between **10:00 hours and 12:00 hours**.

3. **If the** required samples are not submitted within five (5) working days**,** no further sample permits **shall be issued for that application, and the** dossier shall be rejected**.**

14.6 Until it is submitted to MFDA, the temperature must be maintained as per the recommendation by the manufacturer.

14.7 Samples shall tally with the documents submitted for registration, otherwise the application shall be rejected.

14.8 In case an application is rejected, the samples shall be kept in MFDA for 60 days from the date of rejection and then they will be disposed of as per recommended method.

15 Processing of Applications

15.1 Administrative Screening

15.1.1 Upon receipt of the Application through the Dhirithi Portal, MFDA will conduct a document completeness and compliance check within fifteen (15) working days.

15.1.2 If all documents are acceptable, notification of acceptance will be issued through the Dhirithi Portal.

15.1.3 If the product is rejected for any reason, notification of rejection will be issued via Dhirithi Portal.

16 Evaluation of the Application

16.1 Once the application is accepted and submission fees are paid, the evaluation process will begin and will be completed within thirty (30) working

16.2 days.

16.3 Technical assessment of the documents in the application will be performed by the assigned staff of the Regulation Unit, Medicine and Therapeutic Goods Division (MTG).

16.4 The evaluation summary and recommendations will be reviewed and verified by the Section Head.

17 Regulatory Decision

17.1 Upon completion of evaluation, the application and technical findings will be submitted to the Technical Committee on Nutraceuticals (TCN) for review, comments, and recommendations.

17.2 The recommendation of TCN will then be submitted to the National Pharmaceutical Board (NPB) for a final decision regarding approval or rejection.

17.3 If approved from TCN, it will be further processed by submitting it to the National Pharmaceutical Board (NPB).

17.4 Following review, the Division Head and MFDA Head will approve or reject the application based on the evaluation outcomes of the TCN and NPB.

17.5 The final decision will be formally communicated to the applicant within fifteen(15) days after completion of the evaluation process.

17.6 Approval of Product

17.6.1 If the product is approved, an official notification of approval will be issued to the local agent/applicant through the Dhirithi Portal within five (5) working days following the final decision.

17.6.2 A request for payment of the registration fee will be sent to the applicant via the Bandeyri Portal within two (2) working days after the approval notification.

17.6.3 The registration certificate will be issued once MFDA confirms receipt of the full registration fee payment.

17.7 Rejection of a Product

17.7.1 If the product is rejected based on the recommendations of the Technical Committee on Nutraceuticals (TCN) and/or the National Pharmaceutical Board, the decision will be communicated to the applicant via the Dhirithi Portal within five (5) working days of the decision has been made.

The notification will outline the reasons for rejection to support transparency and future improvement.

(Note: Resubmission of an application may be allowed if deficiencies are corrected and a new application is submitted in accordance with MFDA procedures.)

17.8 Issuing Permit

17.8.1 A registration certificate for the approved nutraceutical product will be issued in the official MFDA format.

17.8.2 The certificate will be issued within ten (10) working days from the date the registration fee payment is confirmed, except in exceptional circumstances where additional time is required. Where delays occur, the applicant will be informed in writing.

17.8.3 The validity period of the nutraceutical product registration certificate is five (5) years from the date of issuance, subject to continued compliance with MFDA regulatory requirements.

18 Approved Nutraceutical List

18.1.1 The Approved Nutraceutical List (ANL) is the official list of nutraceutical products that are allowed to be imported, sold, and distributed within the Maldives.
The list is updated monthly on the 10th of each month and published on the Ministry of Health website (www.health.gov.mv).

18.1.2 Once a product is approved and registration fees are paid, it will be included in approved Nutraceutical List for the following month.

19 Re-Registration of Nutraceutical Products

19.1 Application for Re-Registration

19.1.1 Holders of a valid nutraceutical product registration who wish to continue importation and sale of the product after expiry of the current permit are strongly encouraged to apply for re-registration at least forty-five (45) days prior to the expiration date of the existing certificate. This ensures uninterrupted market availability and allows adequate time for document review and issuance of the renewed permit.

19.2 Required Documents for Re-Registration

19.2.1 The following documents must be submitted as part of the re-registration application.

Note: All documents must be prepared and submitted in English language or accompanied by a certified English translation.

1. Company Profile, including:

b. Full name and complete address of the manufacturer, including telephone, fax numbers and email

c. Updated business and manufacturing information

d. Valid Good Manufacturing Practice (GMP) License issued by a recognized regulatory authority

e. Copy of the previous MFDA registration certificate (expiring permit)

f. Product Samples in final commercial packaging:

- Tablets / Capsules: 20 units
- Syrups / Liquids: 2 sealed bottles
- Powder or Granules: 1 commercial jar or equivalent sachet pack

19.2.2 Additional documentation may be requested if considered necessary by MFDA for evaluation purposes.

20 Responsibilities of the Marketing Authorization Holder (MAH)

20.1 The Marketing Authorization Holder (MAH) is the legal entity responsible for the product's compliance throughout its market life. The MAH should ensure the following obligations are fulfilled:

20.2 Regulatory and Safety Responsibilities

20.2.1 Product Traceability and Recall

20.2.1.1 The MAH is responsible for ensuring the traceability of the product across the supply chain and for conducting a timely and effective recall from all wholesalers, pharmacies, and sales outlets in situations involving:

- Safety concerns
- Quality defects

20.2.2 Notification of Changes

20.2.2.1 The Marketing Authorization Holder (MAH) must promptly inform MFDA in writing of any variations related to the following and get approvals prior to the import:

- Packaging and labeling details
- Safety updates or regulatory actions in other countries

20.2.2.2 Any changes for the manufacturing site, dosage form, changes to composition, changes to packaging material will be considered as a new product and shall be applied as a new product.

Any modification must receive prior approval from MFDA before implementation.

20.2.3 Compliance with Laws and Regulations

20.2.3.1 The MAH must ensure full compliance with all applicable laws, regulations, guidelines, and directives enforced by MFDA and national legislation throughout the product's lifecycle.

21 Legal basis and references

a. Medicine Regulation R-46 (2014)

b. Medicine Regulation Amendment R-49 (2016)

c. Health service act (29/2015)

22 References

1. Woo JJY. 2007. Adverse event monitoring and multivitamin-multimineral dietary supplements. *Am. J. Clin. Nutr* 85:323S–24S [PubMed] [Google Scholar]
2. Athalye, M., Vaghela, S., & Bhavsar, N. (2022). The Study of the Registration Guideline of Nutraceutical Products in ASEAN Countries. Retrieved 26 February 2022, from https://www.eurekaselect.com/article/100817
3. Dr. Tomislav Meštrović, P. (2022). Nutraceutical Regulation. Retrieved 26 February 2022, from https://www.news-medical.net/health/Nutraceutical-Regulation.aspx

Nutraceutical Registration Application Checklists

(To be completed and submitted by the applicant through the Dhirithi Portal)

A. Applicant & Regulatory Documentation

#	Document	Requirement	Attached (✓)	Remarks
1	Company Profile	With full details of manufacturer, contact details, product categories, and license status	☐	
2	Manufacturing Site Address	Full physical address, phone, fax, email	☐	
3	GMP Certificate	WHO-type GMP or equivalent; notarized; minimum 6 months remaining validity	☐	
4	Manufacturing License / Free Sale Certificate	Valid, notarized, meets MFDA data requirements	☐	
5	Proof of Registration in Origin / Export Market	Regulatory approval	☐	
6	Notarized Documents	All regulatory certificates notarized and authenticate	☐	
7	MFDA Previous Permit (if re-applying)	Required for re-registration	☐	

B. Product Documentation

#	Document	Requirement	Attached (✓)	Remarks
1	Product Profile	Name, dosage form, full composition, labeling details, usage instructions	☐	
2	Full Ingredient List	Per-unit quantitative composition for all components	☐	
3	Specifications of Finished Product	Quality standards, stability information	☐	
4	Certificate of Analysis (CoA)	Original, signed, dated, numeric results, testing methods listed	☐	

#	Document	Requirement	Attached (✓)	Remarks
5	Nutraceuticals with Herbal Ingredients	Plant profile, safety data, functional claim evidence	☐	
6	Manufacturing Process Flowchart	Flow chart and narrative explanation	☐	
7	Raw Material Documentation	Source, supplier, purity/quality evidence	☐	

C. Labeling Requirements

#	Label Elements	Requirement	Verified (✓)	Remarks
1	Product Name	Brand and generic/INN name	☐	
2	Dosage Form & Strength	Clearly stated	☐	
3	Batch / Lot Number	Present	☐	
4	Manufacturing / Expiry Date	Present with format clearly defined	☐	
5	Storage Conditions	Clearly printed	☐	
6	Instructions for Use	Dose and directions	☐	
7	Intended Use	Functional claim; no therapeutic claims	☐	
8	Manufacturer Details	Full name and address	☐	
9	Country of Origin	Stated	☐	
10	Pack Size	Clearly indicated	☐	
11	Warnings / Precautions	Where applicable	☐	
12	English Language Label	Required	☐	

D. Product Samples

#	Requirement	Submitted (✓)		Remarks
1	Final commercial packaging	Intact, sealed, labeled	☐	
2	Sample quantity	Tablets/Capsules: 20 units; Liquids: 2 bottles; Powder: 1 jar/sachet pack	☐	
3	Shelf-life	Minimum 50% remaining	☐	

#	Requirement	Submitted (✓)		Remarks
4	Label consistent with documentation	Inner label acceptable if no outer box	☐	

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

Nutrient	Current Daily Value
Selenium	55mcg
Sodium	2300mg
Thiamin	1.2mg
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