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Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline on Registration of Nutraceuticals

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It is the property of:
Maldives Food and Drug Authority
Male'
Republic of Maldives

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Guideline on Registration of 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.

This Guideline shall apply to all categories of Nutraceuticals as follows:

1. Products containing vitamins, and minerals (natural & synthetic) with physiological process or specific claims to maintain or enhance a specific body function or structure.

2 PURPOSE

To ensure the safety and quality of the nutraceuticals imported and sold in the Maldives.

3 SCOPE

This guideline has been developed to guide the medicine importers certified and authorized by Maldives Food and Drug Authority in the preparation and submission of Nutraceutical registration in the form of application.

4 RESPONSIBILITY AND ACCOUNTABILITY

1. Assigned staff of Medicine and Therapeutic Goods Division (Regulation Unit)
2. Director, Pharmaceuticals (Regulation)
3. Deputy Director General (Medicine Therapeutic Goods Division)
4. Director General (MFDA)
5. Technical Committee on Approval of Nutraceuticals.

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 and approved by the Technical Committee of Nutraceutical Approval . 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.

Commented [am1]: is this the same committee mtg technical committee? DG is not include in the mtg technical committee.
Should feel we can have a separate committee with DG, Food person and 2 mtg staff- Just and idea

5.2 Submission of Application

5.2.1 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)**

5.2.2 All regulatory certificates must be notarised.

5.2.3 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.

5.2.4 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.

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

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

5.3 General Requirement

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

5.3.2 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.

5.3.3 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.

5.3.4 Specifications of the finished product

5.3.4.1 Provide certificates of analysis for finished product.

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5.3.4.2 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

5.3.5 Labelling Requirements

5.3.5.1 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.

5.3.5.2 The label information should be English.

5.3.5.3 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. Pack Size

k. Warning/precaution if any

5.3.6 Proof that the manufacturing site for the product is GMP compliant (Valid WHO type GMP certificate). GMP certificate should:

a. Bear the name of the firm, the date of certification and identity of 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.

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

5.3.8 Technical documents for raw materials

a. Details of raw material source

b. Proof of quality and purity

5.3.9 Following information about manufacturing process shall be submitted:

a. Flow diagram and the brief description of the process

5.3.10 Certificate of Analysis (CoA) of finished product

5.3.10.1 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.

5.4 Regulatory situation

5.4.1 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).

5.4.2 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

5.4.3 Product samples:

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

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

5.4.3.3 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.

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

5.4.3.5 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.

Commented [am3]: The product sample shall tally with documents submitted

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

5.5 Processing of Application

5.5.1 Once received the dossier from the Dhirithi Portal documents will be checked and verified within 10 (ten) working days.

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

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

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

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

5.6 Evaluation of the application

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

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

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5.7 Regulatory Decision

Technical Committee on Approval of Nutraceuticals makes a regulatory decision based on the outcome of the evaluation of the application. The decision will be accordingly communicated to the applicant. A decision will be made by Technical Committee of Medicine and Therapeutic Goods within 20 (twenty) days after the evaluation has been completed.

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5.8 Approval of Product

a. If the product is approved from the Technical Committee of Medicine and Therapeutic Goods, it will be notified to the Local agent via dhirithi portal 5 working days.
b. The budget slip (registration fees) will be issued.
c. Once the registration fees are paid the certificate will be issued

5.9 Rejection of a Product

5.9.1 If the product is rejected from the Technical Committee, it will be informed to the Local agent via dhirithi portal within 5 (five) working days.

5.10 Issuing Permit

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

5.11 Approved Nutraceutical List

5.11.1 Approved Nutraceutical List (ANL) is the approved list of Nutraceuticals which can be imported and sold with in 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).

5.11.2 Once the product is approved from the technical committee it will be added to the list next month.

5.12 Responsibility of Marketing Authorization Holder

5.12.1 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.

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

5.12.3 Comply with existing Laws, Regulations and Rules.

6 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

7 Legal basis and references

a. Medicine Regulation R-46 (2014)

b. Medicine Regulation Amendment R-49 (2016)

c. Health service act (29/2015)