بسم الله الرحمن الرحيم

Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Registration of Alternative/Herbal Products and Dhivehi Beys

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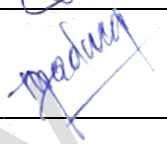
Authorized by	Thooma Adam, Deputy Director General, Laboratory Services (Acting Head of MFDA)	

SUMMARY OF CHANGES

Version No.	Issued Date	Section/Clause	Summary of Change	Changes Made by
1	04.03.2019	-	Creation of the document	Mohamed Fazeen, Director, Pharmaceuticals
2	12.10.2025	Overall Document	Changes to procedure and formatting, addition of quality testing requirements	Mohamed Fazeen, Director, Pharmaceuticals
3	28.12.2026	Overall Document	Name, Changes to procedure and formatting, addition of quality testing requirements	Mohamed Fazeen, Director, Pharmaceuticals

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Definitions

Applicant	The individual or legal entity that applies to the Maldives Food and Drug Authority (MFDA) for the registration of a medicinal product.
Application / Dossier	A complete set of documents and data submitted to MFDA for the purpose of product registration, evaluation, and approval.
Alternative Products / Herbal Medicines	**These** are products derived from natural sources such as plants, minerals, or other non-synthetic substances, which are presented for use in the diagnosis, treatment, mitigation, or prevention of diseases, or for maintaining or improving health, based on traditional knowledge or alternative medical practices. These products may include herbal medicines, traditional medicines Beys), and other non-conventional medicinal preparations, and are regulated based on their composition, intended use, therapeutic claims, and route of administration.
Dhivehi Beys	**Dhivehi Beys** refers to traditional Maldivian medicinal products prepared using indigenous knowledge and practices, primarily derived from natural sources such as plants, minerals, and animal materials. These products are used for the prevention, treatment, or management of illnesses based on long-established traditional use in the Maldives and are recognized and regulated as a category of alternative or traditional medicine by the Maldives Food and Drug Authority.
Approved Alternative/Herbal Products and Dhivehi Beys List	The official list maintained by MFDA containing alternative/herbal medicines that have been evaluated, approved, and registered for importation, distribution, and sale in the Maldives.
Bandeyri Pay	The official government online payment platform used for payment of application submission and registration fees.
Brand Name	The proprietary or trade name assigned to a product by the manufacturer under which it is marketed.
Certificate of Analysis (COA)	An official document issued by a testing laboratory that confirms the quality of a product or raw material based on specified tests, methods, and acceptance criteria.
Certificate of Registration	An official document issued by MFDA confirming that a medicinal product has been evaluated and approved for importation, distribution, and sale in the Maldives.
Composition	The complete qualitative and quantitative list of all active ingredients and excipients present in a product, including strength per dosage unit.

Contaminant Test	Testing performed to confirm that a product is free from harmful contaminants such as heavy metals, pesticides, or other impurities beyond acceptable limits.
Country of Manufacture	The country where the product is manufactured.
Dhirithi Portal	The official online government portal used for submission, processing, and tracking of medicine registration applications in the Maldives.
Dosage Form	The physical form in which a product is manufactured and administered, such as tablets, capsules, syrups, ointments, powders, or shampoos.
Finished Product	The final medicinal product that has undergone all stages of manufacturing, packaging, and labeling and is ready for release and distribution.
Generic Name	The internationally recognized or scientifically accepted name of an active ingredient, not protected by trademark.
Good Manufacturing Practice (GMP)	A system ensuring that products are consistently produced and controlled according to quality standards appropriate for their intended use, as recognized by WHO, PIC/S, or ASEAN authorities.
Heavy Metal Test	A quality control test performed to ensure that levels of toxic metals such as lead (Pb), cadmium (Cd), mercury (Hg), and arsenic (As) are within acceptable limits.
Identification Test	A test conducted to confirm the presence and identity of the declared active ingredient(s) in a product using suitable analytical or organoleptic methods.
Indications / Intended Use	The claimed therapeutic or traditional use of a product as stated by the manufacturer.
Labeling	All written, printed, or graphic information appearing on the immediate container, outer packaging, or accompanying leaflet of a product.
Manufacturer	A company or entity responsible for the production, packaging, labeling, or testing of a medicinal product.
Manufacturing License	An authorization issued by the National Regulatory Authority of the country of origin permitting a manufacturer to produce medicinal products.
Medicine Import Permit	An authorization issued by MFDA allowing an entity to import medicinal products into the Maldives.
Medicine Regulatory Officer	An authorized MFDA official responsible for screening, assessing, and evaluating product registration applications.
Microbial Limit Test	A quality control test conducted to ensure that a product does not contain harmful microorganisms beyond acceptable limits.
Organoleptic Properties	Characteristics of a product such as color, odor, taste, and physical appearance as perceived by the senses.

Packaging	The materials and container closure systems used to enclose and protect a product, including primary and secondary packaging.
Posology	The recommended dose, frequency, duration, and method of administration of a product.
Pre-Screening	An initial review process conducted by MFDA to verify completeness, validity, and legibility of submitted documents prior to full evaluation.
Quality Assurance (QA)	All planned and systematic activities implemented to ensure that a product meets required quality standards.
Quality Control (QC)	Operational techniques and tests used to verify that a product complies with specified quality requirements.
Registration Fee	A non-refundable fee paid by the applicant upon approval of a product prior to issuance of the registration certificate.
Shelf Life	The period during which a product is expected to remain within its approved specifications when stored under defined conditions.
Specifications	Detailed descriptions of quality requirements, test methods, and acceptance criteria for raw materials or finished products.
Stability Data	Scientific data generated through stability studies to support the proposed shelf life and storage conditions of a product.
Storage Conditions	Recommended environmental conditions such as temperature, humidity, and light exposure required to maintain product quality.
Uniformity of Weight / Volume	A quality control test to ensure consistency among individual dosage units in a batch.

1 INTRODUCTION

This Guideline is established to ensure that importers and local manufacturers of Alternative/Herbal Products and Dhivehi Beys /Herbal and Dhivehi Beys comply with the regulatory requirements for the **registration** of such products in the Maldives. It outlines regulatory measures to ensure the safety, identity, strength, quality, and purity of Alternative/Herbal Products and Dhivehi Beys s/Dhivehi Beys products prior to their approval for importation, distribution, and sale within the Maldives.

This Guideline ensures that all Alternative/Herbal Products and Dhivehi Beys submitted for registration are evaluated for quality, safety, and efficacy and that they are manufactured, processed, packed, and held in accordance with Good Manufacturing Practices (GMP). The Maldives Food and Drug Authority (MFDA) implement this Guideline in accordance with the Medicine Regulation 2014/R-46 and under the mandate of the Health Service Act 29/2015.

2 PURPOSE

This Guideline applies to all applicants seeking authorization for the **registration of Alternative/Herbal Products and Dhivehi Beys** in the Maldives. It outlines the procedures and regulatory requirements for obtaining product registration approval under the Medicine Regulation 2014/R-46, prior to importation, distribution, sale, or local manufacture.

3 SCOPE

This Guideline applies to all applicants seeking authorization for the registration of Alternative/Herbal Products and Dhivehi Beys in the Maldives. It outlines the procedures and regulatory requirements for obtaining product registration approval under the Medicine Regulation 2014/R-46, prior to importation, distribution, sale, or local manufacture.

4 RESPONSIBILITY

Medicine Regulatory Officer of Medicine Registration.	Responsible for verifying the documents, accepting the dossiers, evaluating the dossiers, preparing and issuing product registration certificates.

	Is also responsible for effective communication with the applicant in a timely manner
Director Pharmaceuticals (Regulation Section)	Responsible for checking and verifying the product evaluation documents and to guide the Medicine Regulatory Officers on evaluating the product.
Deputy Director General (Medicine Therapeutic Goods Division)	To approve or reject the medicines based on the findings of the evaluation.
Director General (MFDA)	Final authorization of all the activities related to MFDA tasks

5 PROCEDURE

a. Submit Application

b. Product registration application submission.

i. All product registration Applications shall be submitted Online via Dhirithi portal 'https://dhirithi.egov.mv'.

ii. The applicant shall have a medicine import permit issued by Maldives Food and Drug Authority.

iii. Upon receiving the application, the Medicine Regulatory Officer, shall check and ensure all the mandatory documents are submitted and valid.

iv. The following documents shall be submitted:

1. Product Information

No.	Required Information	Description
a	Generic Name	Name given by the manufacturer
b	Brand Name	Name given by the manufacturer
c	Dosage Form	Example: capsule, syrup, ointment, tablet, powder, etc.
d	Composition	Full list of all active ingredients with the strengths and excipients, with scientific, local, and common names, plant part used, and quantity per dosage unit.

e	Description of Product	Physical characteristics (color, odor, form) and organoleptic properties.
f	Intended Use / Indications	Description of claimed traditional use or therapeutic indication.
g	Posology and Route of Administration	Dose and method of administration.
h	Shelf Life	Proposed shelf life with justification from stability data.
i	Packaging Details	Type of primary and secondary packaging materials, container closure system.
j	Storage Conditions	Recommended storage requirements.
k	Labels and Leaflets	Outer pack, inner pack, patient information leaflet (in English and Dhivehi).
l	Product Name	Proprietary and generic name.
m	Brand Name	Name given by the manufacturer

2. Details of the Manufacturer

No.	Required Information	Description
1	Name of Manufacturer	Full legal name.
2	Complete Address	Manufacturing site address including city, country, and postal code.
3	Contact Details	Telephone, fax, email, and website.
4	Country of Manufacture	Specify if product is fully or partially manufactured in multiple countries.
5	Manufacturing Sites Involved	List of all sites involved in production, packaging, labeling, and testing.
6	Organizational Chart (optional)	For complex manufacturers, indicate QA/QC and production responsibilities.

3. Manufacturing License

No.	Document	Details Required
1	Manufacturing License	Issued by the National Regulatory Authority of the country of origin, authorizing the manufacturer to produce Alternative/Herbal Products and Dhivehi Beys s.
2	Scope of License	The license must specify the dosage forms or product categories covered.
3	Validity Period	Must be valid at the time of submission (attach English translation if in another language).

4. Good Manufacturing Practice (GMP)

No.	Document	Details Required
24	GMP Certificate	Issued by a recognized authority (WHO, PIC/S, ASEAN member). Must indicate manufacturing site address and scope.

25	GMP Inspection Report (if applicable)	Copy of latest inspection report or summary from competent authority.
26	GMP Summary	Description of manufacturing facilities, quality management system, and equipment layout (may include facility photos or schematics).

5. Quality Assurance and Control Documents

No.	Document	Details Required
1	Certificate of Analysis (COA)	For finished product and each active ingredient, must include test parameters, specifications, and results (identity, purity, assay, microbial limits, etc.).
2	Specifications of Raw Materials	Including acceptance criteria and analytical methods (pharmacopeial or validated in-house).
3	In-process Quality Control Data	Summary of critical in-process control tests (e.g., moisture, weight uniformity).
4	Finished Product Specification	Description of tests, analytical methods, and acceptance limits for the final product.
5	Microbiological Test Report	Data confirming absence of pathogenic microorganisms.
6	Heavy Metal and Contaminant Test	To confirm that levels of lead (Pb), cadmium (Cd), mercury (Hg), and arsenic (As) are within acceptable limits.
7	Reference Standards	Details of standards used for testing characterization.

6 Quality Assurance Testing for Locally Manufactured Products

6.1 For products manufactured within the Maldives, quality assurance (QA) testing may be conducted in accredited laboratories abroad in cases where the required tests cannot be performed locally. All costs associated with such external testing shall be borne by the applicant or manufacturer.

6.2 Minimum Quality Tests Required for Products Manufactured in the Maldives

6.3 Each locally manufactured herbal or Alternative/Herbal Products and Dhivehi Beys shall undergo, at minimum, the following quality control tests prior to batch release:

No.	Test Parameter	Purpose / Description
1	Identification Test	To confirm the presence of the claimed herbal ingredients using suitable methods (e.g., TLC, microscopy, organoleptic, or chemical assay).
2	Moisture Content / Loss on Drying	To ensure product stability and prevent microbial growth.

3	pH (for liquid preparations)	To verify product consistency and suitability for intended use.
4	Microbial Limit Test	To ensure absence of harmful microorganisms (e.g., *E. coli*, *Salmonella*, *S. aureus*, and *P. aeruginosa*).
5	Heavy Metal Test Contaminant Test	To confirm that levels of lead (Pb), cadmium (Cd), mercury (Hg), and arsenic (As) are within acceptable limits.
6	Uniformity of Weight / Volume	To verify consistency of dosage units (for tablets, capsules, or liquids).

7 Application submission fee

7.1 If all the requirements are complete, the application/dossier shall be accepted and a submission fee of 100 MVR (hundred Maldivian Rufiyaa) shall be paid via Bandeyri Pay (https://bp.finance.gov.mv/), within 5 working days from the time of dossier acceptance to Dhirithi portal. If the payment is not made within the given 5 days, the dossier shall be rejected.

7.2 This submission fee is non-refundable.

7.3 Once the payment is made the evaluation process of the application/ dossiers shall be initiated with regards to safety, quality and efficacy of the product. The evaluation process shall take may take working 60 (sixty) depending on the number of applications pending.

8 Pre-Screening of Dossier

8.1 Once the application/dossier is submitted, it shall be checked for document completion and legibility. If all the requirements as per the acceptance criteria are fulfilled, then only the dossier shall be accepted on 10 (ten)days.

8.2 MFDA shall have the right to reject incomplete dossiers and hence it's the applicant's responsibility to ensure that all are in accordance with the requirements as mentioned.

8.3 Applications/Dossiers that require further clarification shall be put to "Need clarification" status on Dhirithi portal. The clarification requested by the Authority shall be resolved within 10 working days by the applicant, otherwise, the dossier should be rejected.

8.4 In the case of a rejection, the reason for the rejection shall be specified.

8.5 The application/dossier evaluation process may be prolonged due to the time taken by the applicant to respond to the Authority's request to provide additional information or further clarification.

9 Assessment of Application

9.1 Medicine Regulatory Officer of Medicine Registration must act as assessors and verify the required documents, accept the applications/dossiers, and evaluate the applications/dossiers as per approved criteria. In case further clarification is required, these officers are also responsible for effective communication with the applicant in a timely manner.

9.2 A summary of the evaluation is generated in the approved format by the Assessors and submitted before to the Director Pharmaceuticals.

9.3 The Director, Pharmaceuticals (regulation Section) shall cross-review by checking and verifying the product evaluation documents submitted in the dossiers, and to guide the medicine regulatory officers on evaluating the product.

10 Decision by the Deputy Director General, Pharmaceuticals

10.1 Upon successful evaluation of the applications/dossier, the documents are submitted to the DDG, Pharmaceuticals for approval or rejection.

10.2 If recommended to approve the product, the applicant should be notified to pay a registration fee of 300 MVR via Bandeyri Pay within 5 working days. If the payment is not made within the given five days, the client shall be informed via email. If the payment is not made within 10 working days of the notification, the application must be rejected.

10.3 The applicant must process this dossier as a new application again.

10.4 If recommended to reject the product by the DDG, Pharmaceuticals, the dossier shall be rejected, and the applicant shall be notified via Dhirithi portal indicating the reason for rejection within seven (07) working days.

11 Issuance of Registration Certificate

11.1 After the registration fee has been paid, the Authority shall issue a Certificate of Registration of a Drug Product and Agreement to the applicant within 15 working days.

11.2 The applicant shall be notified via email to report to MFDA 2nd floor for the agreement signing and certificate issuance within this period. The applicant shall bear the responsibility of attending the signing and failure to attend within 15 working days of notification shall result in cancellation of the agreement.

11.3 The product can only be imported, distributed and sold in the country once it has been registered and added to the Approved Alternative/Herbal Products and Dhivehi Beys List.

12 Approved Alternative/Herbal Products and Dhivehi Beys List

12.1 Once the medicine has been evaluated and approved to be registered, the product shall be added to the Approved Alternative/Herbal Products and Dhivehi Beys List (MTG/RE-AA/Fo 0010)

13 Re-Registration Process for Alternative Products / Dhivehi Beys

13.1 Submission of Re-Registration Application

13.1.1 Applications for re-registration shall be submitted online via the Dhirithi Portal (https://dhirithi.egov.mv) prior to the 45 days of the expiry of the existing registration.

13.1.2 Applications submitted after the expiry of registration shall not be accepted and shall be treated as a new registration.

13.1.3 The applicant shall hold a valid MFDA medicine import permit at the time of submission.

13.2 Documents Required for Re-Registration

13.2.1 The applicant shall submit the following documents:

a. General Information of the product
b. Detail information of manufacturer
c. Copy of valid Certificate of Registration issued by the country of origin
d. Copy of valid certificate of Registration issued by the MFDA
e. Latest Certificate of Analysis (COA) for the finished product
f. Updated microbiological test report

g. Heavy metal and contaminant test report
h. Valid manufacturing license
i. Valid GMP certificate
j. Updated product labels and patient information leaflet (English/Dhivehi)
k. Declaration confirming whether any changes have occurred since the last registration

13.3 Declaration and Assessment of Changes

a. The applicant shall declare any changes made to the product since the previous registration.
b. Changes may include, but are not limited to, composition, manufacturer, manufacturing site, packaging, labeling, shelf life, or indications.
c. Applications involving significant changes may require full evaluation or submission as a new registration.

13.4 Pre-Screening of Re-Registration Dossier

a. Upon submission, the dossier shall be screened for completeness and validity by MFDA.
b. Incomplete dossiers shall be rejected or placed under “Need Clarification” status on the Dhirithi Portal.
c. The applicant shall resolve all clarification requests within 10 working days, failing which the application may be rejected.

13.5 Evaluation of Re-Registration Application

a. Medicine Regulatory Officers shall evaluate the re-registration dossier to ensure continued compliance with safety, quality, and regulatory requirements.
b. A summary of the evaluation shall be prepared and submitted to the Director, Pharmaceuticals for review.

13.6 Decision on Re-Registration

a. Upon satisfactory evaluation, the dossier shall be submitted to the Deputy Director General (DDG), Pharmaceuticals for approval or rejection.
b. If approved, the applicant shall be notified to pay the prescribed re-registration fee within the specified timeframe.
c. Failure to pay the fee within the stipulated period shall result in rejection of the application.

13.7 Issuance of Re-Registration Certificate

a. Upon confirmation of fee payment, MFDA shall issue a Renewed Certificate of Registration.
b. The product shall remain listed in the Approved Alternative /Herbal and Dhivehi Beys List and may continue to be imported, distributed, and sold in the Maldives.

14 Reference

a. WHO Guidelines for the Assessment of Herbal Medicines (WHO/TRS 863, Annex 11)

b. WHO Guidelines on Good Manufacturing Practices (GMP) for Herbal Medicines (WHO Technical Report Series, No. 937, Annex 3)

c. WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants

d. ASEAN Guidelines for the Registration of Traditional Medicines and Health Supplements

e. Maldives Medicine Regulation (2014/R-46) and amendments