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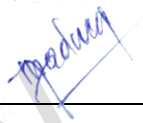
Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Guideline for Registration of Alternative/Herbal Products and Dhivehi Beys

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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	29.12.2025	Overall Document	Name, Changes to procedure and formatting, addition of quality testing requirements	Mohamed Fazeen, Director, Pharmaceuticals
4	29.10.2025	Overall Document	Changes following the publication of Medicine Regulation R-64/2026 Introduction of registration pathways and the new fee structure Addition of checklist Addition of Reference countries list in reliance and other documents	Aminath Ifaaga , Assistant Medicine Regulatory Officer

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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.

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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

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	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.

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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 R-64/2026, 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 R-64/2026, 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 R-64/2026, prior to importation, distribution, sale, or local manufacture.

4 RESPONSIBILITY

Responsible staff/Registration Unit	Responsible for verifying the documents, accepting the dossiers, evaluating the dossiers, preparing and issuing product registration certificates. Is also responsible for effective communication

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	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

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5 PROCEDURE

a. 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:

5.1 Submission of application

5.2 Reliance pathway

5.2.1 Where an alternative medicine product is manufactured in a country listed under **Annex-II – Reference Countries list for Reliance** of this Guideline, the product shall be eligible for evaluation and registration under the Reliance Pathway, subject to fulfilment of the applicable requirements and submission of the required supporting documentation.

5.3 Full dossier pathway

Where an alternative medicine product is manufactured in a country that is not listed under **Annex -II – Reference Countries list for Reliance** of this Guideline, the product shall be evaluated and registered under the Full Dossier Pathway. The applicant shall submit the complete dossier and all supporting documents required for evaluation in accordance with the applicable requirements of this Guideline.

6 Application submission fee

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6.1.1 If all the requirements are complete, the application/dossier shall be accepted, and a **submission fee of MVR 550/- (five hundred and fifty Maldivian Rufiyaa)** shall be paid via **Bandeyri Pay** (https://bp.finance.gov.mv/) within **5 working days** from the time of dossier acceptance in the Dhirithi portal. If the payment is not made within the specified 5 working days, the application/dossier shall be rejected.

6.2 This submission fee is non-refundable.

6.3 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.

7 Pre-Screening of Dossier

7.1 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.

7.2 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.

7.3 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.

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

7.5 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.

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8 Submission Requirements

8.1 General Requirement for all the Pathways

Letter of Appointment as in **Annex I** of this Guideline.
Letter from the manufacture to MFDA as per the format in **Annex-IV**.
Artwork, 360 angle picture of the product with package insert. (Product information leaflet,
MANUFACTURER DECLARATION Regarding Product Safety, Alerts, Recalls, Field Safety Corrective Actions (FSCAs), Safety Notices, Product Sameness, GMP Compliance and Regulatory Actions as in **Annex-III**
○ Clean completed checklist as per registration pathway. • The checklist shall be downloaded from the Publications section of the Dhirithi Portal. • The applicant shall retain only the sections relevant to the applicable registration pathway, including the designated MFDA verification and signature table, and remove all non-applicable sections. • The original format and structure of the checklist shall be maintained without any alterations. • A sample checklist for one registration pathway is provided in **Annex V** for reference.

8.2 Required Documentation under reliance pathway

8.2.1 General Requirements mentioned in 8.1 in this Guideline

8.2.2 Completed checklist as per registration pathway under **Annex-V** in this guideline

8.2.3 Evidence of approval from the country of manufacture

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8.2.4 Evidence of approval in one of the reference countries as mentioned in Annex II of this document. A link should be provided to trace the evidence or registration or marketing authorization certificate.) **(If not traceable via online justification letter shall be provided)**

8.2.5 A valid Good Manufacturing Practice (GMP) (Validity of 06 (six) months shall be there at the time of submission).

8.2.6 Product information for reliance

- Product Name:
- Active ingredients
- Strengths
- Dosage Form
- Indication
- Storage Condition
- Shelf life
- Pack Size

9 Required Documentation under Full Dossier Pathway (Normal Pathway)

9.1 Evidence of Registration

9.1.1 General Requirements mentioned in 10.1 in this Guideline

9.1.2 Evidence of approval by the NRA of the country where the finished dosage form is manufactured

9.1.3 Verifiable declaration of regulatory status in at least 1 other NRAs. For this, a link should be provided to trace the evidence or registration or marketing authorization certificate.

9.1.4 A valid Good Manufacturing Practice (GMP) (Validity of 06 (six) months shall be there at the time of submission).

9.1.5 The GMP certificate must clearly state the name of the manufacturing firm, date of certification, and name of the issuing authority.

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9.2 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

1. 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.

2. Manufacturing License

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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).

3. 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).

4. 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.

10 Product Samples

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10.1 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.

10.2 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.	60 units shall be submitted (e.g. 60 tablets, 60 capsules).

10.1 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.

10.2 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-VI)** shall be submitted via e mail (medicine.registration@health.gov.mv) before handing over the samples.

10.3 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**.

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

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

10.6 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.

11 Quality Assurance Testing for Locally Manufactured Products

11.1 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.

11.2 Minimum Quality Tests Required for Products Manufactured in the Maldives

11.3 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).

12 Assessment of Application

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12.1 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.

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

12.3 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.

13 Decision by the Deputy Director General, Pharmaceuticals

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

13.2 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.

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

14 Registration fee

14.1 If the product is recommended for approval by the DDG, the applicant shall be notified to pay the applicable registration fee via Bandeyri Pay within five (5) working days. The applicable registration fees are as follows:

No.	Type of Registration	Registration Fee (MVR)
1	New registration under the Reliance Pathway	750.00
2	New registration under the Full Dossier Pathway	2,500.00
3	Renewal of registration under the Reliance Pathway	500.00
4	Renewal of registration under the Full Dossier Pathway	1,000.00

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14.2 If the payment is not made within the specified five (5) working days, the applicant shall be informed via email. If the payment is not made within ten (10) working days from the date of notification, the application shall be rejected, and the applicant shall be required to submit the application as a new application in accordance with the applicable MFDA procedures.

15 Issuance of Registration Certificate

15.1 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.

15.2 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.

15.3 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.

16 Approved Alternative/Herbal Products and Dhivehi Beys List

16.1 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)

17 Re-Registration Process for Alternative Products / Dhivehi Beys

17.1 Submission of Re-Registration Application

17.1.1 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.

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

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

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17.2 Documents Required for Re-Registration

17.2.1 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

17.3 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.

17.4 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.

17.5 Evaluation of Re-Registration Application

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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.

17.6 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.

17.7 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.

18 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
f. Medicine Regulation (2026/R-64)

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Annex-I

Letter of Appointment

Maldives Food and Drug Authority

Ministry of Health and Family

Male`, Republic of Maldives

Statement by the Local Applicant for submission of Application

1) I have received and accepted the entire dossier from **Company name and address** for the product **Name of the product, Brand/ Generic/ Dosage Form/ Strength**.

This dossier includes all data in support of the original documents as per the format of MFDA.

2) I hereby agree that I have sole responsibility for the mentioned product including obtaining approvals for any subsequent product variation and maintenance of the product registration.

3) I declare that information submitted in this application is correct and complete. I authorize the Maldives Food and Drug Authority to obtain information from any institution previously or currently associated with my company. If any information supplied by me is considered to be false, incomplete or misleading in any aspect, Maldives Food and Drug Authority has the right to take action as it believes necessary including the disclosure of the information to any person or body the Maldives Food and Drug Authority considers has a legitimate interest in receiving it and I consent to such disclosure. I understand the Maldives Food and Drug Authority reserves the right to vary or revoke any decision made on the basis of untrue, incomplete or misleading information. Moreover, I will co-operate with any person representing the Maldives Food and Drug Authority, by providing additional information or making the manufacturing premises available for inspection as required.

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4) I also acknowledge the responsibility in the event of pharmacovigilance issues or quality defects associated with the product that may occur after the registration.

5) The information provided to the Maldives Food and Drug Authority contain confidential information that can hinder our business and hence this information shall be kept confidential and shall not be disclosed to any third party without our consent.

6) I shall take the responsibility for updating any information relevant to the product/application and will take the initiative to inform MFDA in a timely manner any change in product information during the course of evaluation, and after product registration, especially if the information pertains to rejection/withdrawal and will provide, additional data on product efficacy and safety or current Good Manufacturing Practice (cGMP) compliance of the manufacturers (and repackers, if applicable).

7) I will also supply relevant information in case where the manufacturing facility is sold, merged or changed to another.

8) As the local agent for marketing the product, I shall take full responsibility for assuring the quality, safety and efficacy of this product throughout the supply chain.

Applicant representative information (whom MFDA will contact);

Name:

Phone number

Email:

Signed:
Full Name:
Identity Card Number:
Full Address:
Status of the signatory:
(To be signed by the managing director/president/CEO or an equivalent person who has overall responsibility for the company or organization)
Official company stamp:
Fax Number/Telephone Number:
E mail contact details:
Date:

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Annex-II

Reference Countries List for Reliance

#	Country	Authority	Reliance Scope	Reliance Criteria
1	Australia	Therapeutic Goods Administration	Medicines and Vaccines	A stringent regulatory authority (SRA)
2	Austria	Austrian Agency for Health and Food Safety (AGES)	Medicines and Vaccines	A stringent regulatory authority (SRA)
3	Belgium	Federal Agency for Medicines and Health Products (FAMHP)	Medicines and Vaccines	A stringent regulatory authority (SRA)
4	Bulgaria	Bulgarian Drug Agency	Medicines and Vaccines	A stringent regulatory authority (SRA)
5	Canada	Health Canada	Medicines and Vaccines	A stringent regulatory authority (SRA)
6	Croatia	Agency for Medicinal Products and Medical Devices of Croatia (HALMED)	Medicines and Vaccines	A stringent regulatory authority (SRA)
7	Cyprus	Ministry of Health — Pharmaceutical Services	Medicines and Vaccines	A stringent regulatory authority

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				(SRA)
8	Czech Republic	State Institute for Drug Control (SUKL)	Medicines and Vaccines	A stringent regulatory authority (SRA)
9	Denmark	Danish Medicines Agency	Medicines and Vaccines	A stringent regulatory authority (SRA)
10	Estonia	State Agency of Medicines (Ravimiamet)	Medicines and Vaccines	A stringent regulatory authority (SRA)
11	Finland	Finnish Medicines Agency (Fimea)	Medicines and Vaccines	A stringent regulatory authority (SRA)
12	France	National Agency for the Safety of Medicine and Health Products (ANSM)	Medicines and Vaccines	A stringent regulatory authority (SRA)
13	Ghana	Food And Drugs Authority (FDA)	Medicines and Vaccines	Maturity Level 3, based on WHO GBT Assessment
14	Germany	Federal Institute for Drugs and Medical Devices	Medicines and Vaccines	A stringent regulatory authority (SRA)
15	Greece	National Organization for Medicines	Medicines and Vaccines	A stringent regulatory authority (SRA)
16	Hungary	National Institute of Pharmacy and Nutrition	Medicines and	A stringent regulatory authority

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		(OGYEI)	Vaccines	(SRA)
17	Iceland	Icelandic Medicines Agency	Medicines and Vaccines	A stringent regulatory authority (SRA)
18	Indonesia	BADAN POM (Agency for Drug and Food Control, or Indonesian FDA)	Vaccines	Maturity Level 3, based on WHO GBT Assessment
19	Ireland	Health Products Regulatory Authority	Medicines and Vaccines	A stringent regulatory authority (SRA)
20	Italy	Italian Medicines Agency (AIFA)	Medicines and Vaccines	A stringent regulatory authority (SRA)
21	Japan	Ministry of Health, Labour and Welfare/Pharmaceuticals and Medical Devices Agency	Medicines and Vaccines	A stringent regulatory authority (SRA)
22	Latvia	State Agency of Medicines	Medicines and Vaccines	A stringent regulatory authority (SRA)
23	Liechtenstein	Office of Health / Department of Pharmaceuticals	Medicines and Vaccines	A stringent regulatory authority (SRA)
24	Lithuania	State Medicines Control Agency (VVKT)	Medicines and Vaccines	A stringent regulatory authority (SRA)
25	Luxembourg	Ministry of Health	Medicines and	A stringent regulatory authority

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			Vaccines	(SRA)
26	Malta	Medicines Authority	Medicines and Vaccines	A stringent regulatory authority (SRA)
27	Netherlands	Health and Youth Care Inspectorate (IGZ)	Medicines and Vaccines	A stringent regulatory authority (SRA)
28	Nigeria	National Agency for Food and Drug administration and control (NAFDAC)	Medicines and Vaccines	Maturity Level 3, based on WHO GBT Assessment
29	Norway	Norwegian Medicines Agency	Medicines and Vaccines	A stringent regulatory authority (SRA)
30	Poland	Chief Pharmaceutical Inspectorate	Medicines and Vaccines	A stringent regulatory authority (SRA)
31	Portugal	National Authority of Medicines and Health Products (Infarmed)	Medicines and Vaccines	A stringent regulatory authority (SRA)
32	Republic of Korea	Ministry of Food and Drug Safety (MFDS)intlpharm@korea.kr	Medicines and Vaccines	Maturity Level 4, based on WHO GBT Assessment
33	Romania	National Agency for Medicines and Medical Devices	Medicines and Vaccines	A stringent regulatory authority (SRA)
34	Saudi Arabia	Saudi Food and Drug	Medicines and	Maturity Level 4, based on WHO GBT

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		Authority (SFDA)	Vaccines	Assessment
35	Singapore	Health Sciences Authority (HSA)	Medicines and Vaccines	Maturity Level 4, based on WHO GBT Assessment
36	Slovakia	State Institute for Drug Control (SIDC)	Medicines and Vaccines	A stringent regulatory authority (SRA)
37	Slovenia	Agency for Medicinal Products and Medical Devices (JAZMP)	Medicines and Vaccines	A stringent regulatory authority (SRA)
38	Spain	Spanish Agency of Medicines and Medical Devices (AEMPS)	Medicines and Vaccines	A stringent regulatory authority (SRA)
39	Sweden	Medical Products Agency	Medicines and Vaccines	A stringent regulatory authority (SRA)
40	Switzerland	Swiss Agency for Therapeutic Products (Swissmedic)	Medicines and Vaccines	A stringent regulatory authority (SRA)
41	Tanzania	Tanzania medicines and Medical Devices Authority (TMDA)	Medicines and Vaccines	Maturity Level 3, based on WHO GBT Assessment
42	Türkiye	Turkish medicines and Medical Devices Authority (TITCK)	Medicines and Vaccines	Maturity Level 3, based on WHO GBT Assessment
43	United	Medicines and Healthcare products Regulatory Agency	Medicines and	A stringent regulatory authority

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	Kingdom	(MHRA)	Vaccines	(SRA)
44	United States of America	Food and Drug Administration	Medicines and Vaccines	A stringent regulatory authority (SRA)
45	Zimbabwe	Medicines Control Authority of Zimbabwe (MCAZ)	Medicines and Vaccines	Maturity Level 3, based on WHO GBT Assessment
46	China	National Medicines Products Administration (NMPA)	Vaccines only	Maturity Level 3, based on WHO GBT Assessment
47	India	Central Drugs Standard Control Organization (CDSCO)	Vaccines only	Maturity Level 3, based on WHO GBT Assessment
48	Thailand	Food and Drug Administration	Vaccines only	Maturity Level 3, based on WHO GBT Assessment
49	Egypt	Egyptian Drug Authority (EDA)	Medicines and Vaccines	Maturity Level 3, based on WHO GBT Assessment
50	Ethiopia	Ethiopian Food and Drug Authority (EFDA)	Medicines and Vaccines	Maturity Level 3, based on WHO GBT Assessment
51	Kazakhstan	The committee of Medical and Pharmaceutical control and the National Center of Expertise of Medicine and Medical Devices of the	Medicines and Vaccines	Maturity Level 3, based on WHO GBT Assessment

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		Ministry of health of Kazakhstan		
52	Mozambique	Autoridade Nacional Reguladora de Medicamentos de Moçambique (ANARME)	Medicines and Vaccines	Maturity Level 3, based on WHO GBT Assessment
53	Sénégal	Agence sénégalaise de Réglementation Pharmaceutique	Medicines and Vaccines	Maturity Level 3, based on WHO GBT Assessment
54	Serbia	Medicines and Medical Devices Agency (ALIMS)	Medicines and Vaccines	Maturity Level 3, based on WHO GBT Assessment
55	Viet Nam	Vaccine regulatory system in Vietnam represented by: a) The Drug Administration of Viet Nam (DAV), b) Administration of Science, Technology and Training (ASTT), c) National Institute for the Control of Vaccines and Biologicals (NICVB) and d) General Department of Preventive Medicine (GDPM)	Vaccines	Maturity Level 3, based on WHO GBT Assessment

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Annex-III

[Manufacturer Letterhead]

MANUFACTURER DECLARATION

Product Safety, Recalls, FSCAs, Safety Notices, Product Sameness, GMP Compliance and Regulatory Actions

1. Product and Manufacturer Details

Product Name (Brand Name)	
Generic Name	
Strength	
Dosage Form	
Volume	
Manufacturer Name	
Manufacturing Site Address	
Country of Origin	

2. Declaration

We, the undersigned manufacturer, hereby declare that the information provided concerning the above-mentioned product submitted for registration with the Maldives Food and Drug Authority (MFDA) is true, accurate and complete.

We hereby confirm that:

1. The product is not subject to any unresolved safety alerts, recalls, Field Safety Corrective Actions (FSCAs), safety notices, warnings or other safety-related regulatory actions affecting its safety, quality, efficacy or performance.

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2. The product submitted for registration is identical to the product approved in the country of origin or relevant reference country in terms of composition, strength, dosage form, manufacturing site, specifications and other relevant quality attributes, except for differences declared to and accepted by MFDA.

3. The manufacturing site complies with applicable Good Manufacturing Practice (GMP) requirements and is not subject to any unresolved critical GMP non-compliance findings, regulatory suspensions or restrictions affecting the manufacture of the product.

4. The product has not been subject to any undisclosed registration suspension, cancellation, withdrawal, marketing prohibition, import restriction or other regulatory action in the country of origin or any other country.

5. Any previous safety alerts, recalls, GMP non-compliance findings or regulatory actions have been fully disclosed, together with their current status, corrective actions and supporting evidence, where applicable.

6. We undertake to immediately notify MFDA of any new safety, quality, GMP compliance or regulatory concerns arising during the registration process or throughout the validity of the product registration, in accordance with the applicable notification requirements.

7. We acknowledge that any false declaration, misrepresentation or failure to disclose relevant information may result in rejection, suspension or cancellation of registration, restrictions on future applications or other regulatory measures in accordance with applicable laws and MFDA requirements.

We certify that this declaration is made by an authorized representative of the manufacturer and that all information provided is true and complete as of the date of signing.

3. Authorization

Name of Authorized Representative: _____

Designation: _____

Signature: _____

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Date: _____

Official Manufacturer Stamp: _____

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Annex-IV

[Manufacturer Letterhead]

Letter from manufacturer to MFDA

To: Maldives Food and Drug Authority (MFDA)
Malé, Republic of Maldives

Subject: Authorization of Local Representative for Product Registration

Dear Sir/Madam,

We, [Full Legal Name of Manufacturer], having our registered address at [Full Registered Address], hereby authorize [Full Legal Name of Local Representative], located at [Full Address in the Maldives], to act as our authorized local representative for the purpose of submitting and managing product registration applications with the Maldives Food and Drug Authority (MFDA) on our behalf for the products listed below.

Manufacturer details

Name: [Manufacturer Name]
Registered address: [Full Address]
Contact details: [Email / Telephone]

Authorized local representative

Name: [Local Representative Name]
Address: [Full Address in the Maldives]

Products covered by this authorization

No.	Product name	Strength / dosage form	Manufacturer / site
1	[Product name]	[Strength / form]	[Site]

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This authorization applies solely to the products identified above and remains valid until [Expiry Date / Revocation in Writing]. We undertake to notify MFDA in writing of any change to or withdrawal of this authorization.

Yours faithfully,

For and on behalf of [Manufacturer Name]

Name: [Name of Authorized Signatory]

Designation: [Designation]

Signature: _____

Date: [DD Month YYYY]

Company stamp / seal

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Annex - V

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Rec.No: MTG/RE-ER/Re 0065/2026/000

Checklist for Alternative Medicine Applications

Maldives Food and Drug Authority
Ministry of Health
Male`
Republic of Maldives

1. Registration Pathways		
Reliance (approved by reference NRAs)	**5 years**	☐
Full procedure	**5 years**	☐

2. Registration type (to be filled by MFDA)

Date of Submission	
Date of Acceptance	
A) New Registration	
B) Re-registration	

3. Approved Alternative list status (To be filled by the Applicant)

Product Name (Brand) including strength		
Generic Name		
Number in Published Approved Alternative List		
Price of the product in USD	**Cost Price:**	
	Retail Price:	

4. Product Evaluation Summary

	Client submitted information	**Evaluation Remarks**	**Check and verified**
A. General Information for all applications			
Letter of appointment from the local agent as per the format provided in Annex -I			
Letter from manufacturer to MFDA as per the format provided in Annex -IV			
Manufacturer Declaration as per the format provided in Annex -III			
Artwork, 360 angle picture of the product with package insert.			
B. Information required for Reliance (approved by reference NRAs)			

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1) Evidence of approval from the country of manufacture (A link should be provided to trace the evidence or registration or marketing authorization certificate.)			
2) Evidence of approval and marketing in one reference country as mentioned in Annex II. (A link should be provided to trace the evidence or registration or marketing authorization certificate.)			
3) Product Name			
3.1) Generic Name			
3.2 Compositions including all active and non-active ingredients:			
Component and quality standard	**Function of the component in the formulation**	**Quantity per unit (mg) %**	**%**
Total			
3.4 Product Name			
3.4 Strength:			
3.5 Pharmaceutical form (Dosage form):			
3.6 Indication or Use of the product:			
3.7 Storage conditions:			
3.8 Shelf life of the product:			
3.9 Pack size / Volume:			

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4) Product information required for the Reliance Pathway, as specified in Section 8.2.5 Guideline for Registration of Alternative/Herbal Products and Dhivehi Beys			
5) Physical Sample			

Full Procedure

B. Information required for Full Procedure

1) Evidence of approval by the NRA of the country where the finished dosage form is manufactured and batch release takes place. For this, a link should be provided to trace the evidence or registration or marketing authorization certificate.			
2) Verifiable declaration of regulatory status in at least 1 other NRAs. For this, a link should be provided to trace the evidence or registration or marketing authorization certificate.			
3) Product Name			
3.1 Generic Name			
3.2 Compositions including all active and non-active ingredients:			
Component and quality standard	**Function of the component in the formulation**	**Quantity per unit (mg) %**	**%**
Total			

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3.3 Strength:			
3.4 Pharmaceutical form (Dosage form):			
3.5 Indication or Use of the product:			
3.6 Storage conditions:			
3.7 Shelf life of the product:			
3.8 Pack size / Volume:			
3.10 Certificate of Analysis (COA) for the finished Products			
4) Product information required for the Reliance Pathway, as specified in Section 8.2.5 Guideline for Registration of Alternative/Herbal Products and Dhivehi Beys			
5) Physical Sample			

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FOR MTG TO USE		
Prepared by:		Checked and verified by:
		Director Pharmaceutical
Date:		Date:
OPINION AND RECOMMENDATION OF THE SCIENTIFIC EXPERT COMMITTEE		
APPROVED		
REJECTED		

Chairman's Signature:		
Name:		
Date:		
Approved by:		Authorized by:
Deputy Director General, Pharmaceuticals		Deputy Director General, Health Laboratory Services
Date:		Date:

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Annex-VI

Registration of an Alternative Product
Sample submission form

No	Product Name	Generic Name	Batch No	Strength	Dosage Form	Manufacture/ Company Name	Country	Manufactured date	Expiry Date	Quantity	Local Agent

For office use only		
Received by	**Signature**	**Date**

	MTG/MFDA		Rec.Name: Sample Submission Form		Authorised by: DG, MFDA	
	Rec.No. MTG/RE-SS/Fo 0057		Issued Date: 29/01/2023		Approved by: Pharm.sp MTG	
	Issue No.: 01		Revised Date:		Verified by: Technical Committee, MTG	
	Rev No.: 00		Page &[Page] of &[Pages]		Prepared by: Fathimath Fareesha	

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