بسم الله الرحمن الرحيم

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

Application for marketing authorization of a pharmaceutical product

Serial #	REQUIREMENTS	Dossier Page No.	MFDA USE ONLY
A. Supplier/Marketing Authorization holders information:			
	1) A letter of appointment from the supplier/local agent/marketing authorization holder baring all the responsibilities of the manufacturer in regard to the product. (As per the format given in ANNEX 1)		
B. **Pharmaceutical Product Information sheet**:			
	The following information shall be provided : 1) Product name/Brand Name of the product		
	2) Generic name of the product		
	3) Active pharmaceutical ingredient(s)(use INN if any)		
	4) Non-active ingredients		
	5) Strength per unit dosage unit		
	6) Dosage form		
	7) Pack size: 7.1 Description of primary packing materials 7.2 Weight, volume and Dimension 7.3 Description of secondary packaging material 7.4 Number of units, weight , volume and dimensions 7.5 Number of secondary packs per standard pallet Note: For drug product in plastic container, studies done on the plastic to demonstrate safety to use shall be provided.		
	8) Route of administration		
	9) Therapeutic class		
	10) Proposed dispensing category		

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	11) Shelf life		
	12) Storage condition		
C .Manufacturer of the product:			
	1) Manufacturer responsible for lot release of the finished dosage form. Provide full details of name, address, phone, fax, e-mail and contact details.		
	2)Manufacturer responsible for packaging of the finished dosage form, if different from the above. Provide full details of name, address, phone, fax, e-mail and contact details		
	3) Manufacturing license by the relevant Authority to perform the activity		
	4)Proof that the **product** is a WHO pre qualified product or not		
	5)Proof that the manufacturing site for the **product** is GMP compliant (Valid WHO type GMP certificate) (should have the validity of 06 months at the time of submission)		
	6)The agency approving the GMP of the site		
	7)The proof of validation of the manufacturing method for each standard batch size		
	8)Standard batch size quantities		
	9) Technical specifications of all raw material(s) and source, including steps taken to assure consistent quality of starting materials.		
	10) Brief profile of manufacturer(s), range of products manufactured and marketed in country of origin.		
	11) Brief description of 1) manufacturing plant lay-out and machinery employed. 2) Manufacturing and packaging process of the product.		
	12)List of personnel, their responsibilities and qualifications		
	13) Letter from the manufacturer for registering the product (Manufacturer to the Drug Regulatory Authority)		
	14)Any regulatory decisions taken on this product from any drug regulatory authorities (including recalls, bans alerts etc)		
D. Regulatory situation:			
	1) Evidence supporting the registration status of the product in the manufacturing		
	country and whether or not used in the country		
	2) Evidence supporting that product is registered for export.		
	3) Valid Certificate of Pharmaceutical Product (CPP), in accordance to the WHO Certification Scheme (should have the validity of 06 months at the time of submission)		
	4) List of countries where the product is registered and currently marketed.		
	5) Documentation supporting registration/ licensing status of the product in countries other than country of origin. (from the selected 14 countries as specified by MFDA)		
	6) Free sale certificate of the product		
E. Finish product specification :			
	1) Specify the finish product specification with reference to pharmacopoeia indicating the edition		
	2) Copy of the finish product specification		
	3) Limit in % for the assay in active ingredients(s)		
	4) Additional specifications if any (eg dissolution etc)		

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	5) Copy of the Model certificate of analysis for batch release/Certificate of analysis of finished product		
F. Stability			
	1)Provide the stability testing data for the product		
	2)Specify the conditions for : 2.1 Satisfactory accelerated testing 2.1.1 Type of container 2.1.2 Conditions (temperature/relative humidity/Duration) 2.1.3 Number of Batches 2.1.4 Batch size 2.1.5 Date of study		
	2.2 Satisfactory real time testing 2.2.1 Type of container 2.2.2 Conditions (temperature/relative humidity/Duration) 2.2.3 Number of Batches 2.2.4 Batch size 2.2.5 Date of study		
	3) Is the stability testing done on the product of the same formula, manufactured on the same site and packed in the same packing material as the product that will be supplied?		
G. Therapeutic Equivalence			
	1)Demonstrated with evidence in either of the following way: 1.1 By In vivo bioequivalence studies with a reference product		
	1.2 By in vitro dissolution tests with a reference product		
H. Sample, Label and insert information			
	1)Shelf life		
	2) Storage conditions in detail (Eg Do not store above 30 c, protect from light etc)		
	3)Label Language(Attach a copy)		
	4) Copy of the packing insert		
	5) Samples of the packing with labels (3 nos)		
	6) Free non returnable Product samples: 6.1 Tablets/capsules :60 nos 6.2 syrups : 3 nos 6.3 Injectables : 3 nos		
I. Price			
	1)Cost price in USD		
	2) Proposing price for retailing it in Maldives market in USD		

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Special Notes:

1. On Documents:

(a) Arrange the documents according to the checklist
(b) Table of contents and page number should indicate the location of documents inside the dossier
(c) Use identifying markers/separators in between sections
(d) All regulatory certificates must be notarised
(e) Incomplete documents and/or documents that do not comply with the above-stated notes will not be received.
(f) Documents must be submitted after setting up appointment. You may call +960-3014316, +960-33014317, Medicines and Therapeutic Goods Division, Maldives Food and Drug Authority to set up appointment
(g) The dossier submission fee is MRF 100 and if the product is successfully considered for registration a fee of MRF 300 is charged. The fee has to be paid to the finance section of the Maldives Food and Drug Authority after the dossier is received.

2. On Registration process

(a) Follow-up on the product application status will be through an official letter
(b) The final decision on registration of the products is by the Board for Pharmaceuticals
(c) The Board for Pharmaceuticals and the Maldives Food and Drug Authority registers medicines based on set criteria. All applicants will be informed of the results of the product evaluation process.
(d) Applicants who wish to know why their product has not passed registration may make a formal inquiry if they so desire so that reasons for disqualification may be informed.
(e) Applicants must name a designated person for correspondence including telephone and email address
(f) The address of the MFDA is :

Medicines and Therapeutic Goods Division
Maldives Food and Drug Authority
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Fax: +960-3014315

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ANNEX 1

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Ministry of Health and Family
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Statement by the marketing authorization Holder/Local agent/Supplier

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 the data in support of the original Marketing Authorization as per the format of MFDA.
2) I hereby agree that I have the sole responsibility for the mentioned product including obtaining approvals for any subsequent product variation and maintenance of the product registration.

3) I declare that the 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 untrue, incomplete or misleading in any respect, I understand the Maldives Food and Drug Authority may take such 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 reverse 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.

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

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:
Telephone Number:
Fax Number:
E mail contact details:
Date:

- *The applicant shall be responsible for the product and all information supplied in support of his application for registration of the product. He shall be responsible for updating any information relevant to the product/application. MFDA should be informed 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, additional data on product efficacy and safety or current Good Manufacturing Practice (cGMP) compliance of the manufacturers (and repackers, if applicable).*
- *The applicant shall also supply relevant information in case where the manufacturing facility is sold, merged or changed to another.*
- *Any person who knowingly supplies any false or misleading information in connection with his application for registration commits an offence.*
- *The marketing authorization holder must assume responsibility for the quality, safety and efficacy of his products.*

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Annex 3 of Medicines Regulations: General Criteria for Selecting Medicinal Products for the Maldives Market

New entity to Maldives market ← **APPLICANT PRODUCT** → **Existing entity in Maldives market**

- Is the medicine effective?
- Based on pharmaceutical pharmacological references and clinical data submitted. Information and decisions from other drug regulatory authorities
- If it is a line extension medicine (minor chemical modification to an existing medicinal entity is it more efficacious safer contribute to a therapeutic improvement over existing medicines
-

Is the medicine safe?

- Based on pharmaceutical pharmacological references and safety data submitted. Information and decisions from other drug regulatory authorities
- Has the medicine been in the overseas market for long enough? Post marketing data and type of adverse events

Is the formulation acceptable?

- Favorable pharmacokinetic profile, suiting to patient compliance and nature of disease
- Dosage form easy to administer. Acceptability to patients.
- Stability and shelf life under ICH climatic zone IV
- Generally single active ingredient formulation will be preferred. However combinations are acceptable for Vaccines, HIV, TB medicines, etc. Additionally combinations may be acceptable if the product improves compliance and is more cost effective
- Modified release forms will be considered if the pharmacokinetic profile of the drug product is suitable in terms of the therapeutic objective and available at reasonable cost
- Vitamins and cough syrups should also be registered
- Type of non active ingredients: colorants preservatives etc

Is quality acceptable?

- Manufacturers' profile and standing. Locally and foreign marketed products by type and volume
- Manufacturing license. GMP inspection
- Manufacture of any WHO pre-qualified product(s) like HIV, TB, Vaccines will be used as a positive criteria for only those products.
- Quality with respect to product: Registration status in reference drug regulatory authorities including duration. Reference drug regulatory authorities are USFDA, EMEA including UK MHRA, Health Canada, Therapeutic Goods Administration Australia, DRA New Zealand, Health Science Authority Singapore, NPCB Malaysia, FDA Thailand, Sri-lanka, any other DRA designated on case by case basis.

Are local health problems which influence selection considered?

- Morbidity, mortality , need analysis
- Facilities and professional expertise available

Is the medicine affordable?

- Proposed retail and wholesale price of the medicine

Medicinal product considered for registration.

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