

بِسْمِ اللّٰهِ الرَّحْمٰنِ الرَّحِیْمِ



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

Application for marketing authorization of a pharmaceutical product

Enclosures	REQUIREMENTS	NO. OF COPIES	Dossier Page No.	MFDA USE ONLY
	Applicant information			
1	Letter of appointment as the local agent if the applicant is local	1		
2	Pharmaceutical Product Information sheet. The following information should be provided in this sheet. 1) Product name 2) Active ingredients and non-active ingredients 3) Strength 4) Dosage form 5) Presentation(s) of unit pack 6) Routes of administration 6) Therapeutic class 8) Proposed dispensing category 8) Shelf life 9) Storage conditions: 10) Manufacturer responsible for lot release of the finished dosage form. Provide full details of name, address, phone, fax, e-mail and contact person. 11) 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 person	1		
3	Valid WHO type GMP certificate attesting to the status of the manufacturer as to competency, of personnel, equipment and facilities.	1		

4	Attach copy of most recent GMP inspection conducted at your premises. (If such a document is not available state reasons and provide name and address of competent Drug Regulatory authority in your country)			
5	Valid WHO type Certificate of Pharmaceutical Product	1		
6	Documentation supporting registration/ licensing status of the product in countries other than country of origin. Note the product has to be registered in any other country (Only the Authorities in the list of MFDA) and it has to be over one year for the registration.	1		
7	Any regulatory decisions taken on this product from any drug regulatory authorities (including recalls, bans alerts etc)	1		
	Manufacturing Information			
8	Unit dose and batch formulation	1		
9	Technical specifications of all raw material(s) and source, including steps taken to assure consistent quality of starting materials.	1		
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.	1		
12	List of personnel, their responsibilities and qualifications	1		
13	stability studies of finished product for 3 batches for climatic zone IV	1		
14	Specifications of primary container , and packaging material:	1		
15	For drug product in plastic container, studies done on the plastic to demonstrate safety to use:	1		
16	Labeling materials, label, box, blister/ strip foil	1		
17	Product information Literature/ Product package insert.	1		
18	Product sample for MFDA. Capsules and Tablets 40nos. Injections 10 nos. Syrups 10nos.	1		
19	Certificate of analysis of finished product	1		
	Pharmacology, Pharmacokinetics			
20	Pharmacology, clinical studies with references.			
21	Bioavailability studies for applicable ¹ products	1		
22	Dossier submission statement	1		
23	Proposed retail and wholesale price of the medicine	1		

¹ Consult with Medicines and Therapeutic Goods Section, Maldives Food and Drug Authority

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 +960-3312283, +960-3332608 Medicines and Therapeutic Goods Section, Maldives Food and Drug Authority to set up appointment
- (g) Please provide details to part 10, 11 and 12, only if the same information has not been submitted for other products in the past 12 months
- (h) The dossier submission fee is MRF 200 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 letter and emails.
- (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 the broad reasons for such disqualification may be informed.
- (e) Applicants must name a designated person for correspondence including telephone and email address.
- (f) Applicants may inform MFDA in advance to facilitate customs clearance of samples for product registration

(g) The address of the MFDA is

Medicines and Therapeutic Goods Section,
Maldives Food and Drug Authority
Sosun Magu, Male` Maldives

Phone: +3345721, +960-3332608
Fax: +960-3343539

Dossier Submission Statement to be completed by all applicants

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".

Signature:

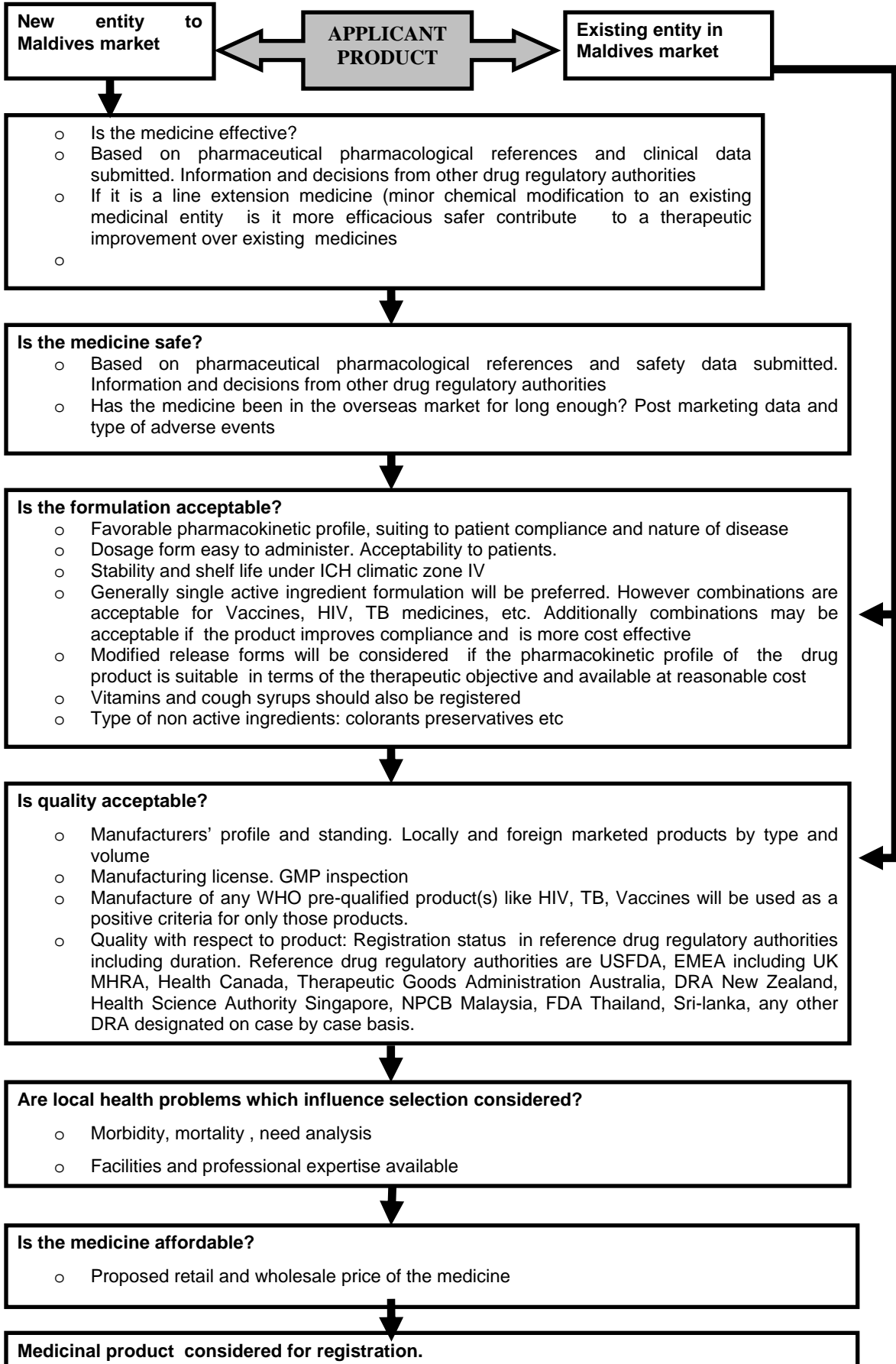
Name:

Designation in the company

Name of applicant company

Date:

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



بِسْمِ اللّٰهِ الرَّحْمٰنِ الرَّحِیْمِ



**Board for Pharmaceuticals
Maldives Food and Drug Authority
Ministry of Health and Family
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List of Drug reference Drug Regulatory Authority for Drug Registration

1. US FDA
2. EU EMEA
3. JAPAN(MIN OF HEALTH LABOR WELFARE)
4. HEALTH CANADA
5. AUSTRALIA (TGA)
6. NEWZELAND
7. SINGAPORE (HEALTH SCIENCE AUTHORITY)
- 8 .MALAYSIA
9. THAILAND
- 10.SRILANKA

Note: Also other authority designated by on a case by case basis.

The Registration Certificate has to over one year of age limit at the time of submitting.