

Maldives Food and Drug Authority Ministry of Health Male', Maldives

Form	Number:	MTG/RE-F	PR/Fo	0041/	'	-	

Clinician's Request for Approval of New Medicine

	Official 3 Request for Approval of New Medicine
	s form may be completed by a clinician, but it must be signed by the Medical Director of t institute.
1.	Brand name:
2.	Generic name:
3-	Dosage form:
4-	Strength:
5-	Pharmacological classification
6-	Clinical indication:
7-	Name of manufacture and country of origin:
	posed category for the medicine (Eg: POM, OTC, Restricted for Hospital and institutional only(HI)):
	What other similar acting drugs and dosage forms are presently included the list of Approved drugs:
9- \ list'	What are the therapeutic advantages of this drug over similar acting drugs already in the ?
0	M/high of the circiles of the day of (a) in the list should be deleted in force of the control of the circulation of the circul
9 - 	Which of the similar acting drug (s) in the list should be deleted in favor of this new drug
11-	Describe the major side - effects reported for this new drug:

Medicine and Therapeutic Goods Division, Maldives Food and Drug Authority			Authorized by: Director General, MFDA		
Rec. No: MTG/RE-PR/Fo 0041 Rec. Name: Clinician's Request for Approval of New Medicine					
Issue No:01	Issue Date:	Prepared by: Director,		Approved by: Deputy	Copy Letter:
	02.07.2018	Pharmaceuticals		Director General,	
Revision No: 01	Revised Date:	Verified by: Technical		Pharmaceuticals	Page No: Page 1 of 2
	19.02.209	Committee of M	ΓG		

12- Wh	nat contradictions and precautions have been designated for this new drug?
13- Inc referer	licate the source of your information about this drug including pertinent publications and nees:
Details	s of requesting Clinician
	me & signature
Depart	ment Date Maldives Medical &Dental Council Registration Number
Clinicia	an Seal
Approv	ved by Medical Director
Full na	me & signature
Date	
Medica	al Director's Seal
Note:	
1.	Upon approval of the requested medicines by the National Pharmaceutical Board, it will be added to ADL for a period of one year.
2.	At the end of one year, if the medicine is not imported, or if the medicine is not registered it will be deleted from ADL.
3.	Please note that this form must be complete as evaluation and approval is based on the information provided by the clinicians. Hence incomplete form will be rejected.
For of	ficial use only
Check	and Received by:
Desigr	nation:
Signat	ure:
Date:	

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