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

Form Number: MTG/RE-PR/Fo 0041/_____ - _____

Clinician's Request for Approval of New Medicine

This form may be completed by a clinician, but it must be signed by the Medical Director of that 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:
……

Proposed category for the medicine (Eg: POM, OTC, Restricted for Hospital and institutional use only(HI)):……

8- What other similar acting drugs and dosage forms are presently included the list of *Approved drugs:*

……
……
……

9- What are the therapeutic advantages of this drug over similar acting drugs already in the list?

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……
……

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:

……
……

12- What contradictions and precautions have been designated for this new drug?

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13- Indicate the source of your information about this drug including pertinent publications and references:

……
……
……

Details of requesting Clinician

Full name & signature

Department Date Maldives Medical &Dental Council Registration Number
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Clinician Seal

Approved by Medical Director

Full name & signature

Date ----------

Medical 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 official use only

Check and Received by:

Designation:

Signature:

Date: