Maldives Food and Drug Authority

Ministry of Health

Male', Maldives

Form Number: MTG/RE-PR/Fo 0041/2025 - _____

Clinician's Request for Approval of New Medicine

This form must be completed by a licensed clinician and endorsed by the Medical Director of the institution. All sections are mandatory. Incomplete forms will be rejected.

Request Type

(Please tick the appropriate option)

☐ New Generic
☐ New Dosage Form / Strength of Existing Generic in the ADL

Section A: Medicine Details

1. **Generic Name:**

2. **Dosage Form:**

3. **Strength:**

4. **Clinical Indication:**

5. **Pharmacological Classification:**

6. **Known Interactions (Drug–Drug and Drug–Food):**

7. **Side Effects (from minor to major):**

8. **Contraindications and Precautions:**

9. **Justification for Request:**
   (Explain the clinical need, importance of including this medicine in the ADL, and the target patient population.)

10. **Similar Drugs in the ADL (For New Generic Requests Only):**

    - Are there any similar-acting drugs already included in the ADL?
      ☐ Yes ☐ No
    - If yes, provide names and details:
    - Specify which drug, if any, should be replaced and justify:

11. **Supporting Literature or Sources:**
    (Attach relevant research articles, clinical guidelines, or authoritative sources. Include URLs or references.)

Section B: Requesting Clinician's Details

- **Full Name & Signature:**

- **Department:**
- **Date:**
- **Maldives Medical & Dental Council Registration Number:**

- **Clinician's Official Seal:**
  (Required)

Section C: Approval by Medical Director

- **Full Name & Signature:**

- **Date:**
- **Medical Director's Official Seal:**
  (Required)

Section D: Official Use Only

- **Checked and Received By:**

- **Designation:**

- **Signature:**

- **Date:**

Important Notes

- Upon approval by the National Pharmaceutical Board, the requested medicine will be included in the Approved Drug List (ADL) for a period of three (3) years.
- If the medicine is not imported or officially registered within this period, it will be removed from the ADL.
- Incomplete submissions will not be considered.