



Adverse Drug Reaction Reporting Form

MALDIVES FOOD AND DRUG AUTHORITY
MEDICINE AND THERAPEUTIC GOODS DIVISION

For MFDA use only

Rec. No.: MTG/OA-SA/FO 0055/ /

A. PATIENT INFORMATION*

NAME: _____

Age at Onset: ____ Years ____ Months ____ Days

DOB: ____/____/____

Sex: M/F

NIC/PPN: _____

If female, pregnant or not: Y/N

Weight (Kg): _____

Other relevant history of the patient (Allergies, Smoking, Alcohol Use, Hepatic/Renal Problems, and Pre-Existing Medical Problems etc.):

B. SUSPECTED DRUG(S)/VACCINE(S)* (use additional pages if necessary)

Name of Drug (Brand Name & Generic Name)	Strength	Dosage Form	Manufacturer / Country of Origin	Batch No.	Route of Administration and Administered Dose	Date Started	Date Stopped

Reason for Use: _____

C. ADVERSE REACTION EXPERIENCED/OBSERVED*

Date of onset of reaction:

Does reaction subside after suspect drug discontinuation? Yes No

Outcome of the event:

Recovered Hospitalized Disability Unknown Death, If Died, date of death(D/M/Y):

Description of adverse event (specify if any laboratory test have done):

Treatment for reaction:
Results:

D. REPORTER INFORMATION*

Reporter Name:

Institution:

Designation & Department:

Mobile Number:

E-mail Address:

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Received By:

Date:

Signature:

Action Taken:

IMPORTANT NOTES:

- Please ensure that all sections are filled especially the mandatory fields identified by *.
- Report any suspected reaction or event at the earliest (preferably within 24hours) from any pharmaceutical product, vaccine, biological, vitamins & minerals, supplements, herbal medicine/traditional medicines and any radiopharmaceutical.
- Provide as much details as possible, attached additional sheets/reports of investigations to ensure full assessment of the event.

----- Please send the form to: mtg.vigilance@mfa.gov.my -----