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:

DOB: ___/___/_____

NIC/PPN:

Age at Onset: ____Years ____ Months ___ Days

Sex: M/F

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@mfda.gov.mv ------