ADVERSE DRUG REACTION REPORTING FORM

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Sr. No

REPORT ON SUSPECTED SERIOUS ADVERSE DRUG REACTION

For Report to
Drugs Controller
Pak Secretariat, Block C,
Ministry of Health,

1. PARTICULARS OF PATIENT

Name of patient. _____

Age _____ Weight (kg) _____ Patient address _____

Sex ☐ Male Race _____

☐ Female

Pregnant ☐ Yes ☐ No ☐ Not applicable

Relevant Medical History _____

_____

2. ADVERSE EVENT

Reason for reporting

☐ Requires or prolongs hospitalization ☐ Life threatening ☐ Death

☐ Permanently disabling or incapacitating ☐ Congenital anomaly ☐ Overdose

☐ Other (Please Specify) _____

_____

3. SUSPECTED DRUG

Name of suspected Drug _____ Generic Name _____

Name of manufacturer _____

Date of occurrence _____ Duration of Event _____

Starting date of Medication _____

Route of administration _____

Discontinuation of Drug because of event ☐ No ☐ Yes Dated _____

_____

4. REPORTING DOCTOR'S / PHARMACIST'S / NURSE'S SIGNATURE _____

Institution _____

Date _____

GUIDELINES TO FILL SERIOUS ADVERSE EVENT REPORT FORM

An adverse event is "Serious", if it

- Is life threatening
- Results in hospitalization
- Prolongation of hospitalization
- Causes malignancy
- Is an overdose resulting in clinically Relevant signs and / or symptoms
- Results in permanent disability
- Is associated with death
- Causes a birth defect
- Causes a relevant organ toxicity

An adverse drug event can be a manifestation of various etiologies such as

- Complication of an underlying disease
- Coincidental accident
- Concomitant medication
- Intercurrent disease
- Drug associated effect