SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

For Health Care Professionals

For Pharmacy Use Only

Report No.

A. PATIENT DETAILS

Patient's Initials or Name:_____Identification Number (Medical/Hospital Ref):_____
Sex: **Male/Female**:_____, If Female, **pregnant or not:**_____Age (at the time of reaction):_____Weight (kg) _____

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

Drug/Vaccine/Alternative Medicine (Brand Name & Generic Name)	Batch No:	Manufacturer /importer	Route of Administration &Daily Doses	Dosage & Strength	Start Date	Stop Date	Prescribed For

C. SUSPECTED REACTION(S) *(use additional pages if necessary):*

1. When reaction started (DD/MM/YY):_____**2.**When recovery started (DD/MM/YY):_____

3.Describethereaction(s):*(use additional pages if necessary):*

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

5.Relevant tests/Laboratory data with dates: *(use additional pages if necessary):*

6. Do you consider the reaction(s) to be serious? Yes/No
If yes, please tick all that apply of the following:

- ☐ Patient died due to reaction:
- ☐ Life Threatening:
- ☐ Involved or prolonged inpatient hospitalization :Involved
- ☐ persistent or significant disability or incapacity:
- ☐ Congenital anomaly/Birth Defects:

Other Serious(Medically Important Condition):please give details:

7. Reaction abated after use stopped or dose reduced?
☐ **Yes** ☐ **No** ☐ **Doesn't apply**

8. Reaction reappeared after reintroduction.
☐ **Yes** ☐ **No** ☐ **Doesn't apply**

9.Outcomes:
☐ Fatal ☐ Recovering ☐ Unknown
☐ Continuing ☐ Recovered
Other _____

10.Youconsider the problem related to which of the following:
☐ Quality Problem ☐ Medication Error ☐ Adverse Event/Reaction
If other, please specify_____

D. OTHER CONCOMITANTDRUG(S)/VACCINE(S)/ALTERNATIVE MEDICINE(S) *(use additional pages if necessary):*

Drug/Vaccine/Alternative Medicine (Brand Name & Generic Name)	Batch No:	Manufacturer /importer	Route of Administration& Daily Doses	Dosage & Strength	Start Date	Stop Date	Prescribed For

E. SUSPECTED MEDICAL DEVICE(S) fill this area for suspected Device only *(use additional pages if necessary):*

Medical Device Common Name/Brand Name	Lot No/ Batch No:	Manufacturer /importer	Model No:	Unique Identifier No:	Serial No:	If Implanted enter date	If Explanted enter date

F. REPORTER DETAILS

Name:_____**Professional Address**: _____
_____**Specialty**:_____**Tel.No**:
_____,**email Address:**_____**Date of this report**:_____
_____**Signature**_____

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GUIDELINESFORADVERSEDRUGREACTION (ADR) REPORTING

"ADVERSE DRUGREACTION (ADR) REPORTING IS ETHICAL AND MORAL DUTY OF HEALTHCARE PROFESSIONALS"

Please use this form for reporting:

- Suspected Adverse Drug Reactions for **ALL MEDICINES**
- Suspected Adverse Drug Reactions for **NEWMEDICINES**
- Suspected Adverse Drug Reactions for **ALLVACCINES**
- Serious*Suspected Adverse Drug Reactions for **ALLUNREGISTEREDMEDICINES**
- Serious* Suspected Adverse Drug Reactions for **ALL ALTERNATE REMEDIES** used in Homeopathic/ Herbal/ Unani/Ayurvedic Treatment

✓ Reactions which are fatal, life threatening, disabling or incapacitating, resulting or prolong hospitalization, congenital anomaly or birth defect and other serious medically important conditions are considered serious.

✓ Health care professionals shall comment on the causal relationship of each suspected drug/vaccines/alternative medicine with each reaction as per **Naranjo causality assessment scale** which comprises of the following four categories, namely:

i. Certain ii. Probable iii. Possible iv. Unlikely

"This form neither has any legal value nor can be presented before any Court of Law as Evidence."

For the Greater Good & in Public Interest, Please Report ADRs to Pharmacy even if you are unsure.

For More Information/Queries, please contact:

Jehan Zeb Khan, Lead Clinical Pharmacist

jehanzebkhan86@gmail.com, WhatsAPP: 03005822913.

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SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

(Additional page)

B. SUSPECTED DRUG(S)/VACCINE(S)/ALTERNATIVE MEDICINE(S) *(continued)*:

Drug/Vaccine/Alternative Medicine (Brand Name & Generic Name)	**Batch No:**	**Manufacturer /importer**	**Route of Administration &Daily Doses**	**Dosage & Strength**	**Start Date**	**Stop Date**	**Prescribed For**

C. **SUSPECTED REACTION(S)** *(continued)*:

3.Describe the reaction(s) *(continued)*:
4.Other relevant history of the patient (Allergies, Smoking, Alcohol Use, Hepatic/Renal Problems, and Pre-Existing Medical Problems etc. *(continued)*:
5.Relevant Tests/Laboratory Data with Dates *(continued)*:

D. OTHER CONCOMITANTDRUG(S)/VACCINE(S)/ALTERNATIVEMEDICINE(S) *(continued)*:

Drug/Vaccine/Alternative Medicine (Brand Name & Generic Name)	**Batch No:**	**Manufacturer /importer**	**Route of Administration &Daily Doses**	**Dosage & Strength**	**Start Date**	**Stop Date**	**Prescribed For**

E. SUSPECTEDMEDICALDEVICE(S) *(continued)*:

Medical Device Common Name/Brand Name	**Lot No/ Batch No:**	**Manufacturer /importer**	**Model No:**	**Unique Identifier No:**	**Serial No:**	**If Implanted enter date**	**If Explanted enter date**