SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

This form is for voluntary reporting of adverse drug reactions caused by therapeutic goods marketed in Pakistan.

For Health Care Professionals

Pakistan National Pharmacovigilance Centre (PNPC)
Pharmacy Services Division, Drug Regulatory Authority of Pakistan (DRAP)
Ministry of National Health Services, Regulation & Coordination,
3rd Floor, TF-Complex, 7-Mauve Area, G-9/4, ISLAMABAD.
Telephone No: +92519262087

For DRAP's Office 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. Describe the reaction(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. You consider the problem related to which of the following:
☐ Quality Problem ☐ Medication Error ☐ Adverse Event/Reaction
If other, please specify_____

D. OTHER CONCOMITANT 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**

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**_____
Have you reported this problem to Provincial Pharmacovigilance Centre or Manufacturer? If yes, please specify: _____

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

SECOND FOLD HERE

GUIDELINES FOR ADVERSE DRUG REACTION (ADR) REPORTING

"ADVERSE DRUG REACTION (ADR) REPORTING IS ETHICAL AND MORAL DUTY OF HEALTH CARE PROFESSIONALS"

Please use this form for reporting:

- Suspected Adverse Drug Reactions for **ALL MEDICINES**
- Suspected Adverse Drug Reactions for **NEW MEDICINES**
- Suspected Adverse Drug Reactions for **ALL VACCINES**
- Serious* Suspected Adverse Drug Reactions for **ALL UNREGISTERED MEDICINES**
- 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, result in 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 World Health Organization (WHO) causality assessment scale which comprises of the following six categories, namely:

i. Certain ii. Probable iii. Possible iv. Unlikely v. Unclassified vi. Unclassifiable

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

For More Information/Queries, please contact:

Pakistan National Pharmacovigilance Centre (PNPC), Drug Regulatory Authority of Pakistan, Telecom Foundation (TF) Complex, 7-Mauve Area, G-9/4, ISLAMABAD, Pakistan.

Website: ***www.dra.gov.pk*** **Email:** ***pnpc*****.drap@gmail.com.**

FIRST FOLD HERE

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

This form is for voluntary reporting of adverse drug reactions caused by therapeutic goods marketed in Pakistan.

For Health Care Professionals (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 CONCOMITANT 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**

E. SUSPECTED MEDICAL DEVICE(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**