SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

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

For Healthcare Professionals

National Pharmacovigilance Centre (NPC)
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: +92519107413

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."

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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 with **THERAPEUTIC GOODS**
- Suspected Adverse Drug Reactions with **NEW THERAPEUTIC GOODS**
- Suspected Adverse Drug Reactions for **ALL VACCINES**
- **LACK OF EFFICACY** in the case of vaccines, contraceptives, antibiotics, and lifesaving medicines.
- Adverse outcome due to suspected **QUALITY PROBLEM** in therapeutic good.
- Adverse outcomes as a result of an overdose, abuse, misuse, off-label use or medication errors.

✓ **THERAPEUTIC GOODS** include the following: Drugs, Vaccine, Biological or alternative medicine or medical devices or biologicals or other related product as may be notified by DRAP

✓ Fatal reactions, 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/vaccine/alternative medicine with each reaction as per the 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:

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

Website: www.dra.gov.pk **Email:** ***npc@dra.gov.pk***

Phone No: 051-91-7413 & 051-9107299

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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**

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