

SUSPECTED ADVERSE DRUG REACTION REPORTING FORM

This form is for voluntary reporting of adverse drug reactions caused by drugs/vaccines marketed in Pakistan

For Health Care Professionals

National Pharmacovigilance Centre

Pharmacy Services Division

Drug Regulatory Authority of Pakistan (DRAP)

Ministry of National Health Services, Regulation & Coordination

ISLAMABAD

www.dra.gov.pk

For DRAP's Office Use Only

Report No. _____

PATIENT DETAILS

Patient's Name: _____ Sex: **M / F**: _____

Identification Number (Medical/Hospital Ref): _____ Age (at the time of reaction): _____ Weight (kg) _____

SUSPECTED DRUG(S)/VACCINE(S):

Drug/Vaccine	Batch	Route of Administration	Dosage	Date Started	Date Stopped	Prescribed For

SUSPECTED REACTION(S)

When Reaction Started (dd/mm/yy): _____ When Recovery Started (dd/mm/yy): _____

Describe the reaction(s):

Relevant History of the patient (Allergies, Pregnancy, Smoking, Alcohol Use, Hepatic/Renal Problems, Pre-Existing Medical Problems etc:

Seriousness of the reaction(s):

Death: _____ Yes/No
Life Threatening: _____ Yes/No
Hospitalization: _____ Yes/No
Disability: _____ Yes/No
Congenital Malformation: _____
Required to prevent damage/permanent impairment _____ Yes/No
Any Other: _____

Relevant Tests/Laboratory Data with Dates:

Outcomes:

Fatal _____ Recovering _____ Unknown _____
Continuing _____ Recovered _____ Other _____

REPORTER DETAILS

Name & Professional Address: _____

Tel: _____

Email: _____ Specialty: _____

Signature: _____ Date: _____

CLINICIAN (IF NOT THE REPORTING PERSON)

Name & Professional Address: _____

Tel: _____

Email: _____

Specialty: _____ Date: _____

Return in Confidence to: National Pharmacovigilance Centre, Pharmacy Services Division, Drug Regulatory Authority of Pakistan, 3rd Floor, Telecom Foundation (TF) Complex, 7-Mauve Area, G-9/4, ISLAMABAD, Pakistan or Email to drap.pharmacy@gmail.com

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

FREEPOST ADR REPORTING FORM

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GUIDELINES FOR ADR REPORTING

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, or medically significant are considered serious.

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, Drug Regulatory Authority of Pakistan, Telecom Foundation (TF) Complex,
7-Mauve Area, G-9/4, ISLAMABAD, Pakistan. Website: www.dra.gov.pk*

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