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	**CLINICIAN (IF NOT THE REPORTING PERSON)**
Name & Professional Address: _____	Name & Professional Address: _____
_____	_____
_____Tel: _____	_____Tel: _____
Email: _____ Specialty: _____	Email: _____
Signature: _____ Date: _____	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

SECOND FOLD HERE

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

FIRST FOLD HERE