# 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 |
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## 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 |
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## 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 |
|---|---|---|---|---|---|---|---|
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## 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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# 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** |
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## 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** |
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## 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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