سلطنة عُمان
وزارة الصحة
SULTANATE OF OMAN
MINISTRY OF HEALTH

Directorate General of Pharmaceutical Affairs & Drug Control
Pharmacovigilance & Drug Information Department

CONFIDENTIAL

Suspected Adverse Drug Reactions (ADRs) & Drug Related Problems Reporting Form
Drugs/ Herbal Medicines/ Health Products/ Biological Products

1 Patient Details

Patient initial(s): Date of Birth/Age: Sex: ☐M ☐F (Pregnant/ not pregnant) Weight (Kg):
Nationality: M.R.No:

2 Suspected Medicine/ Herbal/ Health Product/ Biological

		Drug Name		Date started	End Date	Daily Dose	Dosage form	Route	BN	MF	Indication
		Trade	Generic								
Suspected											
Concomitant											

3 Suspected Reaction(s)/ Quality Problem(s)/ Medication Error(s)

Description of Reaction(s)/ Quality Problem(s)/ Medication Error (s):	Date of Onset: / /20 Date Stopped: / /20
	Outcome of Reaction: Recovered ☐ Recovering ☐ No Improvement ☐ Fatal ☐ Unknown ☐
	Seriousness of reaction: Patient died☐ Life-threatening ☐ Permanently Disability☐ Hospitalization☐ Congenital Abnormality☐ Other☐……
	Additional Notes (medical history, test results, allergies, dechallenge, rechallenge, pregnancy etc. Attach papers if necessary)

4 Reporter Details

Name:
Profession: ☐ Physician ☐Pharmacist ☐ Nurse ☐ Dentist ☐Other HCP……..
Address: Institution: Governorate: Wilayat:
Tel No: **Email**:
Signature: **Date**:

Kindly submit the report to:
Department of Pharmacovigilance & Drug Information
Directorate General of Pharmaceutical Affairs & Drug Control, Ministry of Health
P.O.BOX: 393, Muscat, PC: 100, Sultanate of Oman
Phone: 22357688 / 22357687 / 22357686, **Fax:** 22358489
Email: mohphar@omantel.net.om

Please Turn Over

Guidelines for Reporting

This form can be used by:	**Use this form to report adverse dug reactions, medication errors & quality problems from:**
• Physician. • Pharmacist. • Dentist. • Nurses. • Other healthcare providers.	• Drugs • Herbal Medicines • Health Products • Biological Products (e.g. Vaccines)

Confidentiality: Reporter's and patient's identity are held in strict confidence by *Pharmacovigilance & Drug Information Department*, information provided by the reporter will be strictly protected and will not be used in any way against him / her.

Adverse Drug Reaction (ADR) is a response to a medicinal product which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function.

Medication Error: is an unintended failure in the drug treatment process that leads to, or has the potential to lead to, harm to the patient (prescribing, dispensing, storing, preparation and administration of a medicine).

Quality Problems:

- ☐ Suspected counterfeit product.
- ☐ Suspected contamination.
- ☐ Suspected pharmaceutical defects
- ☐ Product non-compliant with specification (chemical/ physical/ microbial)
- ☐ Poor packaging or labeling.
- ☐ Therapeutic failure.
- ☐ Others……..

Number of samples affected in the batch ☐
Please provide sample

.....Thank you.....