Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
MUSCAT

سلطنة عمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

To:
Pharmacist Incharge, Armed Forces Hospital (Al Khoudh & Salalah)
Director of Pharmaceutical Care, Royal Hospital
Director of Pharmaceutical Care, Khoula Hospital
Pharmacist Incharge, Al Nahda Hospital
Director of Pharmaceutical Care, DGHS, Muscat Governorate
Director of Pharmaceutical Care, DGHS, Al Dakhliya Governroate
Director of Pharmaceutical Care, DGHS, South Batinah Governorate
Director of Pharmaceutical Care, DGHS, North Batinah Governorate
Director of Pharmaceutical Care, DGHS, Al Dhahira Governorate
Director of Pharmaceutical Care, DGHS, North Sharqiya Governorate
Director of Pharmaceutical Care, DGHS, South Sharqiya Governorate
Director of Pharmaceutical Care, DGHS, Musandam Governorate
Director of Pharmaceutical Care, DGHS, Dhofar Governorate
Director of Pharmaceutical Care, DGHS, Al Wusta Governorate
Director of Pharmaceutical Care, DGHS, Buraimi Governorate
Director of Pharmaceutical Care, DGMS
Pharmacist Incharge, Al Massarah Hospital
HOD, Pharmacy Department, Sultan Qaboos University Hospital
Pharmacist Incharge, Royal Oman Police
Pharmacist Incharge, The Diwan
Pharmacist Incharge, The Sultan's Special Force
Pharmacist Incharge, Internal Security Services
Pharmacist Incharge, Petroleum Development of Oman
Pharmacist Incharge, LNG Oman
ALL PRIVATE PHARMACEUTICAL ESTABLISHMENTS

After Compliments,

Enclosed please find our Circular No.84..... dated 23/12/18. regarding reporting of Suspected Adverse Drug Reactions & Drug Related Problems Reporting Form.

Cc:
DG – for kind inf.
SH (PV-Human Medicines)
SH (PV-Herbal Medicines)
Supdt. of Drug Information

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩ – البريد الإلكتروني: mohphar@omantel.net.om
P.O. Box : 393 Muscat - Postal Code : 100 - Tel.: 22357111, Fax: 22358489 - E-mail: mohphar@omantel.net.om

Sultanate of Oman
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Circular No. 84/ 2018

15 -04-1440 H
23 -12-2018

Official National Adverse Drug Reactions (ADR) reporting Form for reporting ADR and other drug related problems

This has reference to Circular No. 2/2017 dated 04/01/2017, Guide for reporting Adverse Reactions and quality problems and Circular No. 62/2017 dated 16/11/2017 on Reporting of any suspected Adverse reactions, Drug Quality problems and medication errors referring to the Circular No. 5/2017 dated 12th November 2017 issued by H.E The Undersecretary for Health Affairs regarding the reporting procedures.

This is issued now to notify all reporters to use the official national Suspected Adverse Drug Reactions & Drug Related Problems Reporting Form (enclosed form) issued by the Department of Pharmacovigilance & Drug Information, (DPV&DI) for reporting of suspected Adverse drug reactions or Quality problems / Medication errors.

There may be different forms in circulation for reporting Adverse Reactions, including our old ADR form or forms developed by different directorates or institutions. With effect from 01/01/2019, it is made known to all our reporters to kindly stick to the official National Reporting form for reporting to the DPV&DI, which is attached with this circular.

The Governmental Health Institutions are encouraged to use the Vigiflow, which is an online platform for reporting adverse reactions or quality problems or medication errors to the DPV&DI. For using the Vigiflow, it is required to register as a PV Regional Centre and obtain individual user name and Password for the reporters. Those who have already become a member, kindly encourage your staff members to make reports on the Vigiflow, for those who have not yet become a regional centre, are required to do so, and staff from DPV&DI will train the reporters to do the online reporting through vigiflow.

The reporters can also use other mode of reporting which are the MOH website, eSehaty mobile application, email (dg-padc@moh.gov.om) and Fax (23258849).

The Pharmaceutical companies, can continue sending the CIOMS form in PDF format or xml/E2B format.

Kindly cooperate with the above instructions for a unified procedure for reporting ADR and other drug related problems.

Ph. Hussain Al Ramimmy
DIRECTOR OF PHARMACOVIGILANCE & DRUG INFORMATION

ص.ب: ٣٩٣ مسقط – الرمز البريدي: ١٠٠ – هاتف: ٢٢٣٥٧١١١ – فاكس: ٢٢٣٥٨٤٨٩ – البريد الإلكتروني: mohphar@omantel.net.om
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سلطنة عُمان
وزارة الصحة
SULTANATE OF OMAN
MINISTRY OF HEALTH

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

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	Date Stopped	Daily Dose	Dosage form	Strength/ volume	Route	BN	MF/ ED	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: dg-padc@moh.gov.om

Please Turn Over

Guidelines for Reporting

This form can be used by:	**Use this form to report adverse drug 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

Abbreviations:

M: Male
F: Female
M.R.No: Medical Record Number
BN: Batch Number
MF: Manufacturing Date
ED: Expiry Date
HCP: Healthcare Professional

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