دائـــــرة الـــصـــحـــة
DEPARTMENT OF HEALTH

Pharmacovigilance program **برنامج اليقظة الدوائية**

Adverse Reaction Reporting Form
Suspected to be related to Medical Products

(Please complete as much as possible, but do not be put off reporting because some details are missing)

A. Patient Details (See Confidentiality section)

Name:_____ ***Age / D.O.B** _____ ***Health Care Institution:** _____

***Sex:** ⊙ Female ○ Male **Weight (kg):**_____ ***Medical Record No:** _____

Patient contact Details:

B. Medical products used:

		*Medical product Name "Generic & Brand" (Manufacturer and Batch No. if known)	Dose, Route and Frequency	*Therapy Starting Date	Therapy Stopping Date	Indications
Suspected	1					
	2					
	3					
Others	1					
	2					
	3					

Please check in case of ☐ **Medication Error** ☐ **Drug Abuse** ☐ **Self Medication** ☐ **Poisoning**

C. Adverse Reaction

***Description of the reaction(s):**

***Onset date of reaction:** | **End date of reaction:**

Action taken towards Adverse Reaction:

☐ Drug withdrawn ☐ Dose reduced ☐ Dose increased
☐ Dose not changed ☐ Unknown ☐ Not applicable

Reaction abated after use stopped or dose reduced:
☐ Yes ☐ No ☐ Not applicable

Reaction reappeared after reintroduction:
☐ Yes ☐ No ☐ Not applicable

Treatment of Adverse Reaction:
○ No ⊙ Yes(medications and/or other therapy) include dates

Relevant tests / laboratory data including dates:

Other relevant History, including pre-existing medical conditions (e.g. allergies, pregnancy, smoking, renal dysfunction etc)

D. *Outcome of Adverse Reaction

☐ Recovered ☐ Recovering ☐ No improvement ☐ Unknown

E. *Seriousness of Adverse Reaction: ○ **Serious (If yes, tick all applicable below)** ⊙ **Non serious**

☐ Death (include date) ☐ Life threatening ☐ Permanent Disability ☐ Hospitalization
☐ Prolonged hospitalization more than 24 hr ☐ Congenital Anomaly
☐ Required intervention to prevent permanent impairment/ damage ☐ Others Serious ……

F. If this is a follow up report of an already reported AR case, please tick this box ☐

G. *Reporter Details. (Name and complete address) *Profession (Specialty):
Date of filling report:

Phone: Fax : E-mail: Signature:

* indicates mandatory fields **Report no:**

Pharmacovigilance

Pharmacovigilance is the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems. The scope of Pharmacovigilance also covers safety monitoring of herbal medicines, traditional and complementary medicines, blood products, biologicals, vaccines and medical devices.

- **Adverse reaction** An **adverse reaction (AR)** is a harmful and unintended response to drugs. This includes any undesirable patient effect suspected to be associated with drug use. Unintended effect, drug abuse, overdose, interaction (including drug-drug and drug-food interactions) and unusual lack of therapeutic efficacy are all considered to be reportable adverse reactions.

- **A serious adverse reaction** is any untoward medical occurrence that at any dose:
    - results in death
    - requires hospitalization or prolongation of existing hospitalization
    - causes congenital malformation
    - results in persistent or significant disability/incapacity
    - is life-threatening

- **The value of reporting AR to Pharmacovigilance Program is to**
    - Improve patient care and safety in relation to the use of medicines and all medical and paramedical interventions.
    - Improve public health and safety in relation to the use of medicines.
    - Contribute to the assessment of benefit, harm, effectiveness and risk of medicines, encouraging their safe, rational and more effective (including cost-effective) use; and
    - Promote understanding, education and clinical training in pharmacovigilance and its effective communication to the public.

- **What to Report**

  Report all /suspected Adverse Reactions from:
    - Pharmaceutical products (Prescription and non-prescription drugs)
    - Herbal Medicines
    - Traditional and complementary Medicines
    - Vitamins and Minerals
    - Blood derived products
    - Biologicals
    - Radiopharmaceuticals
    - Disinfectants

  For Vaccines, use the Adverse Event Following Immunization (AEFI) Form, posted on Department of Health website or through the e-notification system.

- **Reporting by Whom**

  Health care professionals including medical doctors, dentists, pharmacists, nurses and other allied health professionals are the preferred source for reporting an AR. Anyone including consumers, patients, caregivers, etc can also report an adverse reaction (preferably through their health care professional).

- **When to report**

  Expedited reporting of serious AR's is required as soon as possible, but in no case later than 24 hours of initial receipt of information by health care professional. All other AR's should also be reported at the earliest, but not later than 15 calendar days.

- **How to Report**
    - Fill out the AR reporting form
    - Attach additional information (if needed)
    - Use a separate form for each patient
    - Report online through the e-notification system (Preferred method), or send this form to Department of Health- Abu Dhabi pharmacovigilance program by email / fax

- **Confidentiality**

  Any information related to the identity of the patient and / or the reporter of the adverse reaction will be protected to the fullest extent of law and will not be used in anyway against him.

For submitting the completed AR forms or for more information on reporting, please contact:

Department of Health- Abu Dhabi Pharmacovigilance Program
Tel: 02 4193 496 Fax: 02 4193 668 Email: pharmacovigilance@haad.ae
Online e-notification system: https://bpmweb.haad.ae/UserManagement/MainPage.html