التاريخ: ٤ / ٣ /٢٠١١

تعميم إداري رقم (١٣٦) لسنة ٢٠١١

السادة / مدراء المناطق الطبية المحترمين

السادة / مدراء المستشفيات والمراكز الصحية الحكومية و الخاصة المحترمين

السادة / الاطباء العاملين بالمستشفيات و المراكز الصحية الحكومية و الخاصة المحترمين

السادة / الصيادلة العاملين بالمستشفيات و المراكز الصحية الحكومية و الخاصة المحترمين

السادة / الممرضين العاملين بالمستشفيات و المراكز الصحية الحكومية و الخاصة المحترمين

السادة / الصيدليات الخاصة المحترمين

الموضوع : الابلاغ عن الآثار الجانبيةللدواء و الأخطاء الطبية لاستخدام الدواء

حفاظا على المصلحة العامة و صحة المجتمع ، يسرنا أن نرفق لكم استمارة الابلاغ عن رصد الآثار الجانبية للمنتجات الطبية المستخدمة في المؤسسات الصحية بالقطاع الحكومي و الخاص بالدولة و التي اعتمدت من قبل اللجنة الوطنية لليقظة الدوائية ،حيث يجب ملؤها من أحد ممارسي الرعاية الصحية في هذه المؤسسات.و ارسالها للعنوان التالي :

ادارة التسجيل و الرقابة الدوائية بوزارة الصحة هاتف رقم : ٠٢٦١١١٧-٣٩١/٣١٨ فاكس رقم : ٢٦٢٣١٣٧٤٢ ،بريد الكتروني pv@moh.gov.ae أو ص.ب. رقم : ٨٤٨ .

و ذلك ليتم دراستها و تحليل البيانات من قبل الفريق المختص و اتخاذ الاجراءات اللازمة.

و تفضلوا بقبول فائق الاحترام و التقدير

د.أمين حسـين الأميري

وكيل الوزارة المساعد للممارسات الطبية و التراخيص

مديرة ادارة التسجيل و الرقابة الدوائية

نسخة لكل من:

معالي / وزير الصحة الموقر

سعادة / وكيل وزارة الصحة المحترم

سعادة / المدير العام لوزارة البيئة و المياه المحترم

سعادة / المدير العام لهيئة الصحة – أبو ظبي المحترم

سعادة / المدير العام لهيئة الصحة – دبي المحترم

سعادة / المدير العام لهيئة الإمارات للمواصفات و المقاييس المحترم

سعادة / المدير العام لجهاز أبوظبي للرقابة الغذائية المحترم

سعادة / المدير التنفيذي لمدينة دبي الطبية المحترم

سعادة / مدير إدارة ترخيص الممارسات الطبية/التراخيص الصحية المحترم

سعادة / مديرة إدارة التسجيل و الرقابة الدوائية المحترمة

UAE National Pharmacovigilance Centre مركز دولة الامارات العربية المتحدة الوطني لليقظة الدوائية

Report No:

Reporting Form of Adverse Reaction
Susceptible 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:**
Weight(Kg) :	**Sex:** □ **M** □ **F**	**City :**
Medical Record No:	**Patient contact Details:**	

B. Products used:

		Product Name "Generic & Brand" (Manufacturer and Batch No. if known)	Dose, Route and Frequency	Starting Date	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) :

Starting date of reaction:	**End date of reaction:**

Action taken towards Adverse Reaction:

□ Drug withdrawn □ Dose reduced □ Dose increased
□ Dose not changed □ Unknown □ Others

Reaction abated after use stopped or dose reduced: (De-challenge) □ Yes □ No □ Not applicable	**Reaction reappeared after reintroduction: (Re-challenge)** □ Yes □ No □ Not applicable

Treatment Given to patient for the 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 (Tick all applicable)

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

F. If this is a follow up report of an already reported AR case, please place an 'X' in this box ☐

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

Phone: Fax : E-mail: Signature:

Please turn over

Adverse Reaction (AR) Reporting Guidelines

- **Pharmacovigilance** - The science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other drug-related problems.
- **Adverse reaction-** 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 reaction.
- **A serious adverse reaction** is any untoward medical occurrence that at any dose:
  - results in death
  - requires hospitalization or prolongation of existing hospitalization
  - results in persistent or significant disability/incapacity
  - is life-threatening
- **Medical products:**
  Medical products for the purpose of this document include pharmaceutical products (prescription and non prescription drugs), vitamins and minerals, herbal medicines, traditional medicines, biotechnology products and biologically-derived products such as vaccines, serums, and blood derived products; cells, tissues and organs; disinfectants and radiopharmaceuticals.
- **The value of reporting AR to pharmacovigilance center 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.
- **Reporting by Whom?**
  Health care providers including but not limited to medical doctors, pharmacists, nurses, dentists, allied health professionals, mid wives, etc are the preferred source for reporting an AR. But anyone including consumers, patients, caregivers, etc can also report an adverse reaction to Medical products (preferably through their health care provider).
- **What to Report?**
  All suspected adverse reaction should be reported, especially those that are:
  - Unexpected, regardless of their severity (i.e. not consistent with product information or labeling) or
  - Serious, whether expected or not; or
  - Reaction to recently marketed Medical products (on the marketed for less than five years), regardless of their nature or severity.
- **When to report?**
  Expedited reporting of serious AR's is required as soon as possible, but in no case later than 15 calendar days of initial receipt of information by the health care provider.
- **Confidentiality:**
  Any information related to the identity of the patient and / or the reporter of the adverse reaction will be protected to the fullest extend of law and will not be used in anyway against him.
- **How to Report?**
  - Fill out AR report form
  - Attach additional information, if needed
  - Use a separate form for each patient.
- **Whom to Report to?**
  - Healthcare institutes and professionals should report to UAE Ministry of Health, Registration and drug control department, Pharmacovigilance section.
  - Healthcare institutions and professionals based in Abu Dhabi Emirate should report to Health Authority Abu Dhabi
  - Healthcare institutions and professionals based in Dubai Emirate should report Dubai Health Authority.

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

1. UAE Ministry of Health
Registration and Drug Control Department
Tel: 02 6117 389/329/391/318
Fax: 02 6313742
P.O. Box: 848 Abu Dhabi
Email: pv@moh.gov.ae

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2. Health Authority Abu Dhabi(HAAD)
Fax: 02 4496679
Email: PV@haad.ae
Toll free: 800424