Health Authority Abu Dhabi

Reference Number: PHP/PHM/P0001/09
Issue Date: May 2009
Revision Date: May 2011
Version: 1

1. PURPOSE

The purpose of the policy is to guide the health care providers, consumers and public on the method of reporting suspected adverse reactions experienced from any of the medical products marketed / consumed in the Emirate of Abu Dhabi.

2. POLICY STATEMENT

2.1 Health Authority Abu Dhabi (HAAD) mandates all health care providers to report any /suspected adverse reaction experienced from any of the medical products, soon after the reaction occurred, even if they are not certain that a particular medical product was the cause.

2.2 All suspected adverse reactions (AR) should be reported, especially those that are:

2.2.1 Unexpected, regardless of their severity, i.e., not consistent with product information or labeling; or

2.2.2 Serious, whether expected or not; or

2.2.3 Reactions to recently marketed drugs / medical products (being on the market for less than five years), regardless of their nature or severity.

2.3 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 the health care provider. All other AR’s should also be reported at the earliest but in no case later than 15 days. If any additional medically relevant information is received for a previously reported case, the reporting time clock is considered to begin again for submission of the follow up report.

2.4 HAAD encourages voluntary reporting of all adverse reactions experienced by public and consumers to their health care provider in the beginning. The health care provider can provide additional clinical information that can make the reports more complete and scientifically valid to help Health Authority Abu Dhabi to evaluate the event.
2.5 All reporting should be done in the AR reporting form (Appendix 1). Applicable sections of the AR reporting form should be filled in as complete as possible.

2.6 Any information related to the identity of the patient and/or the reporter of the AR will be protected to the fullest extent of law and will not be used in any way against him.

3. **APPLICABILITY**

The policy is applicable to all health care providers (private and government) and public in the Emirate of Abu Dhabi.

4. **RESPONSIBILITY**

4.1 It is the responsibility of all health care providers and health facility management to comply with the requirements of the policy.

4.2 HAAD to monitor the compliance of AR reporting by health care providers through regular audit and inspection visits.

5. **PROCEDURE**

5.1 The HAAD Pharmacovigilance Center will oversee the AR reporting of all / suspected adverse reactions within the Emirate of Abu Dhabi.

5.2 The AR reporting form (see appendix 1) must be used by health care providers and consumers (preferably in conjunction with their health professional, so that information about medical history can be included in order to make the reports more complete and scientifically valid) to report a suspected AR for any medical products marketed in the Emirate of Abu Dhabi.

5.3 The AR reporting form is made available by HAAD to all health care facilities (private and public) in the Emirate of Abu Dhabi. It is the responsibility of the health care facility management to ensure the availability of the concerned AR forms in their facilities. The reporting form can also be accessed electronically via http://www.health.ae/pdic, and is also available from HAAD Pharma / Medicines and Medical Products Department.

5.4 All applicable sections of the AR reporting form should be filled in as complete as possible. A separate form should be used for each patient and additional pages may be attached if more space is required.

5.5 The completed AR reporting form may be forwarded electronically via http://www.haad.ae or by email or by fax. It can also be submitted directly to the appropriate Centre (see contact information below). HAAD will acknowledge the receipt of adverse reaction report by fax / email. It is very important to note the ‘report number’ provided in the acknowledgement letter for any further follow up in this regard.

5.6 Any follow-up information for an AR that has already been reported should be communicated again by fax or email using a new reporting form. It can also be submitted directly to the appropriate Centre (see contact information below).
order that this information can be matched with the original report, indicate that it is follow-up information, and if known, the date of the original report and the case report number provided in the acknowledgement letter. **It is very important that follow-up reports are identified and linked to the original report.**

5.7 An advisory committee constituted at HAAD will provide expert opinion and recommendations to initiate further actions on the reported cases. The committee will have representation according to the expertise available from the disciplines of general medicine, pharmacy, clinical pharmacology, clinical toxicology, pharmacogenetics, epidemiology, pharmacoepidemiology, pathology, drug regulation and quality assurance, drug information, communications, ethnopharmacology, phytochemistry, traditional complementary and alternative Medicine.

5.8 The committee will give its recommendations on:

- Maintaining quality standards in data collection and assessment procedures
- Data interpretation
- Publication of information
- Follow up action required.

5.9 Based on the advisory committee recommendation, HAAD will follow up with all the concerned parties and decide whether actions need to be taken in the light of the information obtained, by changing in product safety information, for instance, adding a new adverse event, interaction, warning or contra-indications etc.

5.10 In serious cases all health care providers and/or public will be notified of the new information through the HAAD health advisory / circular and print / visual media. The decision on the recall of products, if needed, will be instituted in accordance with HAAD policy for recall of drugs and health care products. (Please refer HAAD policy for recall of drugs and health care products, Reference no: PPR/DMP/DR/0001).

5.11 For more information on AR reporting, additional copies of AR reporting forms or to report an AR, health care providers, public and consumers are invited to contact the following address through any of their preferred means: 
**Health Authority Abu Dhabi Pharma / Medicines and Medical Products Department Pharmacovigilance Center.**
Phone: 02 4193 586, 348, 580. Fax: 02 449 6679 Email: pv@haad.ae.

6. DEFINITION AND ABBREVIATIONS

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Abbreviation</th>
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<tbody>
<tr>
<td>AR</td>
<td>Adverse Reaction</td>
</tr>
<tr>
<td>HAAD</td>
<td>Health Authority Abu Dhabi</td>
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<tr>
<td>WHO</td>
<td>World Health Organization</td>
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</table>
Adverse Reaction

An adverse reaction 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 reaction.

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.

Consumer

A person who is not a health care professional such as a patient, friend, or relative of a patient.

Health care provider

Health care provider includes but not limited to medical doctors, pharmacists, nurses, dentists, allied health professionals, mid wives, caregivers etc.

Serious adverse reaction

A serious adverse reaction is one that requires in patient hospitalization or prolongation of existing hospitalization, causes congenital malformation results in persistent or significant disability or incapacity, is life threatening or results in death. Adverse reactions that require significant medical intervention to prevent one of these listed outcomes are also considered to be serious.

7. CROSS REFERENCES


2. Safety monitoring of Medicinal products, Guidelines for setting up and running a pharmacovigilance centre. The UPPSALA Monitoring Centre http://www.who-umc.org

4. Reporting and evaluating suspected adverse reactions during the development and following the marketing authorisation of medicinal products in the European Economic Area (EEA), Eudravigilance. Also available at http://eudravigilance.emea.europa.eu/human/index.asp


6. The International society of Pharmacovigilance. Also available at http://www.isoponline.org/


8. Good pharmacovigilance practice. MHRA. Also available at http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodPharmacovigilancePractice


8. APPENDIX

Adverse Reaction Reporting Form
# Adverse Reaction Reporting Form

**Health Authority Abu Dhabi**
Pharmacovigilance Centre

**Adverse Reaction Reporting Form**

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)

<table>
<thead>
<tr>
<th>Name:</th>
<th>Age / D.O.B</th>
<th>Health Care Institution:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex: M</td>
<td>D.O.B:</td>
<td>Health Care Institution:</td>
</tr>
<tr>
<td>F</td>
<td>Weight (kg):</td>
<td>Medical Record No:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Patient contact Details:</th>
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</thead>
</table>

## B. Medical products used:

<table>
<thead>
<tr>
<th>Medical product Name &quot;Generic &amp; Brand&quot;</th>
<th>(Manufacturer and Batch No. if known)</th>
<th>Dose, Route and Frequency</th>
<th>Therapy Starting Date</th>
<th>Therapy Stopping Date</th>
<th>Indications</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
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</tbody>
</table>

Others:

<table>
<thead>
<tr>
<th>Medical product Name &quot;Generic &amp; Brand&quot;</th>
<th>(Manufacturer and Batch No. if known)</th>
<th>Dose, Route and Frequency</th>
<th>Therapy Starting Date</th>
<th>Therapy Stopping Date</th>
<th>Indications</th>
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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 not changed
- Dose reduced
- Dose increased
- 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:

- Yes (medications and/or other therapy) include dates.
- No

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)

<table>
<thead>
<tr>
<th>Name:</th>
<th>Profession (Specialty):</th>
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Date of filing report:

Phone: | Fax: | E-mail: | Signature: |
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Report no: |