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DEPARTMENT OF HEALTH

DOH STANDARD ON REPORTING SUSPECTED ADVERSE DRUG REACTIONS AND ADVERSE EVENTS FOLLOWING IMMUNIZATION

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Applies to:	All Healthcare Professionals and Healthcare Providers in the Emirate of Abu Dhabi
This document should be read in conjunction with related UAE laws, DOH Standards, Policies and Manuals.	

1. Purpose

The purpose of this Standard is to set the requirements of reporting suspected adverse drug reactions (ADRs) and adverse events following immunization (AEFI) experienced from using medical products marketed/available in the Emirate of Abu Dhabi.

2. Scope

The standard is applicable to all healthcare providers & professionals in the Emirate of Abu Dhabi.

3. Definitions and Abbreviations

Adverse Drug Reaction (ADR)	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 reportable adverse reactions.
Adverse Event Following Immunization (AEFI)[1]	Is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

[1] WHO Vaccine Safety Basics e-Learning course, Module 3: Adverse Events Following Immunization, Available at: https://vaccine-safety-training.org/classification-of-aefis.html

Medical Products	Medical Products for the purpose of this document include pharmaceutical products (prescription and nonprescription 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.
Healthcare Provider[2]	Any person who operates a healthcare facility or in selected instance, who proposes to do so. For these purposes: • 'person' means any individual or legal entity, that person 'operates' a healthcare facility if he carries on the business of providing healthcare services at the facility or, • where healthcare services are not provided as part of a business, otherwise has the ultimate responsibility for the management of the facility.
Healthcare Professional	An individual who provides clinical professional services within a named healthcare profession
Serious adverse event[3]	A serious adverse event is any undesirable experience associated with the use of a medical product in a patient resulting in at least one of the following: • Death • Life-threatening condition • Hospitalization (initial or prolonged) • Disability or Permanent Damage • Congenital Anomaly/Birth Defect • Required Intervention to Prevent Permanent Impairment of a body function or permanent Damage to a body structure. • Other serious events that do not fit the above outcomes, but may jeopardize the patient and may require medical or surgical intervention (treatment) to prevent one of the above outcomes.

4. Duties of Healthcare Providers and Healthcare Professionals

4.1. Healthcare Providers should:

4.1.1. Develop organizational policies and implement mechanisms to identify, document and report any/suspected ADR & AEFI from the use of medical products to the Department of Health (DOH) Pharmacovigilance Program.

[2] DOH Policies. Available at: https://www.doh.gov.ae/en/resources/policies
[3] What is a Serious Adverse Event? Available at: https://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm ,

4.2. Healthcare professionals should:

4.2.1. Report any/suspected ADR or AEFI experienced from using medical products, soon after the reaction occurred, even if they are not certain that a particular medical product was the cause.

4.2.2. Document the ADR / AEFI in the patient's medical record to prevent recurrence of the case whenever applicable.

4.2.3. Encourage patients to report to them any ADRs & AEFIs experienced. Healthcare professionals can provide additional clinical information prior to sending reports to DOH which will make the reports more complete and scientifically valid.

5. Reporting Requirements

5.1. All suspected ADRs and AEFI should be reported, especially those that are: [4]

5.1.1. Unexpected, regardless of their severity, i.e. not consistent with product information or labelling.

5.1.2. Serious, whether expected or not, or

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

5.2. Expedited reporting of serious ADRs and AEFI is required as soon as possible, but in no case later than 24 hours of initial receipt of information by the Healthcare Provider.

5.3. All other ADRs and AEFI should also be reported at the earliest but in no case later than 30 days.

5.4. 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.

6. ADR/AEFI Reporting Specifications

6.1. An online reporting form is accessible through the E-notification tool which is available at DOH website via the following link: https://bpmweb.doh.gov.ae/usermanagement/login.aspx?Home=1

6.2. Applicable sections of the ADR /AEFI reporting form should be filled in as complete as possible.

6.3. If more than one patient was affected by the same ADR/ AEFI, separate reports for the same incident must be completed and submitted. Additional pages may be attached if more space is required.

6.4. DOH will acknowledge the receipt of ADR/AEFI reports. Any follow up of a reported ADR/AEFI case should be made by mentioning the 'unique report number' provided to the reporter.

[4] Introduction to Post-marketing Drug Safety Surveillance: Pharmacovigilance in FDA/CDER; Also available at https://www.fda.gov/downloads/AboutFDA/WorkingatFDA/FellowshipInternshipGraduateFacultyPrograms/PharmacyStudentExperientialProgramCDER/UCM487405.pdf; accessed August 2018.

6.5. Any information related to the identity of the patient and/or the reporter of the ADR & AEFI will be protected to the fullest extent of law and will not be used in any way against him.
6.6. DOH may provide the reporter/provider with recommendations to initiate further actions on the reported cases if necessary.
6.7. Important safety concerns emerging from ADR/AEFI reports will be communicated to healthcare professionals/providers through circulars, alerts or advisories as deemed necessary by DOH.
6.8. For enquiries on ADR/ AEFI reporting, healthcare providers may contact:

Department of Health Abu Dhabi/ Drugs & Medical Products Department
Pharmacovigilance Program
E-mail pharmacovigilance@doh.gov.ae
Phone: 02 419 3496/3576.

7. Enforcement and Sanctions

DOH may impose sanctions in relation to any breach of requirements under this standard in accordance with the Chapter on Complaints, Investigations, Regulatory Action and Sanctions Policy, Healthcare Regulator Manual.