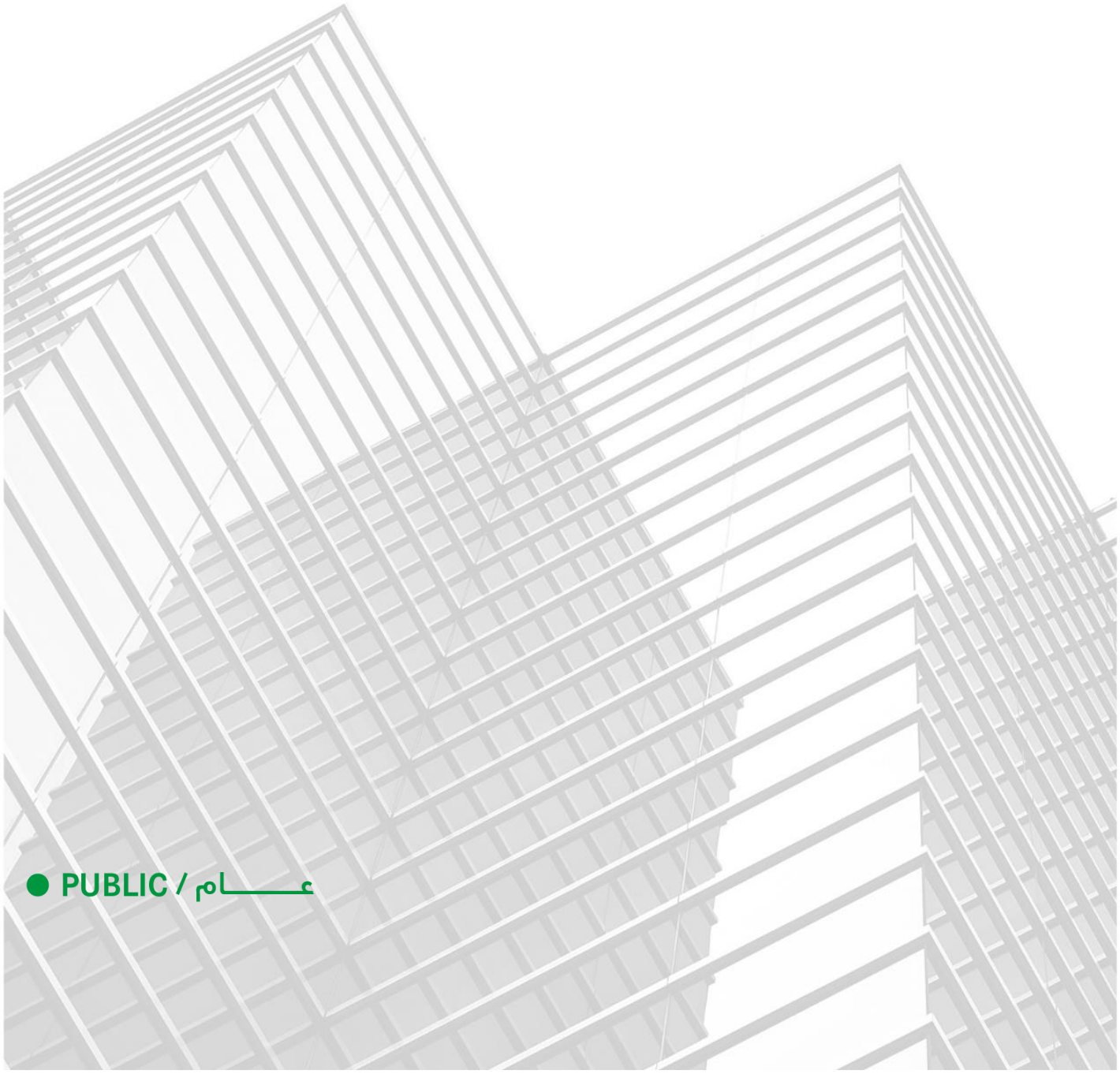
دائـــــرة الـصـــحـــة
DEPARTMENT OF HEALTH

Standard On Reporting Suspected Adverse Drug Reactions and Adverse Events Following Immunization



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1.Standard Scope

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.

The standard applies to all DoH licensed healthcare providers and professionals in the Emirate of Abu Dhabi, which intend to assist healthcare professionals in the participation of very important process of continuous surveillance of safety and efficacy of the medical products which are used in their clinical practice. Continuous evaluation of medicines' benefit and harm help to achieve the ultimate goal of safe and effective treatments available to patients.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	Adverse Drug Reaction (ADR)[1]	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.
2.2	Adverse Event Following Immunization (AEFI)[2]	Is any untoward medical occurrence following immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.
2.3	Department of Health (DoH)	Department of Health Abu Dhabi
2.4	Healthcare Provider[3]	Any person who operates a healthcare facility or in a 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.
2.5	Healthcare Professional	An individual who provides clinical professional services within a named healthcare profession
2.6	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.

2.7	Serious adverse event[4]	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.

3.Standard Requirements and Specifications

3.1 All suspected ADRs and AEFI should be reported, especially those that are: [5]

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

3.1.2. Serious, whether expected or not.

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

3.1.4. Increased frequency of a given reaction is suspected.

3.1.5. ADRs occurring from overdose or medication error.

3.1.6. Lack of efficacy with medicines used for the treatment of life-threatening diseases (e.g. antimicrobial agents), vaccines or contraceptives or other classes of medicines where lack of efficacy could result in serious consequences, require reporting. Normal progression of disease does not imply lack of efficacy. The batch/lot number of the suspected medicine for a report of lack of efficacy must be included in the report.

3.2. 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.

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

3.4. 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.

3.5. 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

3.6. The reporter must complete all applicable sections of the ADR/AEFI reporting form as thoroughly as possible. This is critical for high-quality case reports. The quality of these reports directly impacts pharmacovigilance team ability to assess the relationship between a product and any adverse reactions; thus, a report shall have the following elements:

3.6.1. Patient information, including the name or initials, age, sex, weight, and baseline medical condition prior to product therapy, allergies, co-morbid conditions, use of concomitant medications, relevant family history of disease, and presence of other risk factors.

3.6.2. Suspected adverse reaction:

3.6.2.1. Description of the adverse reaction or disease experience, including time

to onset of signs or symptoms and the seriousness of the reaction/s.

3.6.2.2. Patient outcomes (e.g., hospitalization or death)

3.6.3. Suspected and concomitant medicines details (i.e., Name, concentration, dose, dosage form, route of administration, indication for use, duration of use and batch number especially for vaccines), including over-the-counter medications, dietary supplements, and recently discontinued medications.

3.6.4. An identifiable reporter (Name, Address, Contact details).

3.6.5. Any other relevant information (e.g., other details relating to the reaction or information on benefits received by the patient, if important to the assessment of the reaction).

3.7. At least the above four sections (3.6.1 until 3.6.4) should be completed to have a valid report. these four sections are the minimum information which allows the case report to be valid subsequently to enter the ADRs onto the VigiFlow® system, the WHO global database and become available for signal generation in order to facilitate evaluation of cases. When one or more of this information is missing, the case will be followed up by the DoH pharmacovigilance team in order to validate the report and complete its processing as described above.

3.8. 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.

3.9. Acknowledgement of the receipt of ADR/AEFI reports will be system generated.

3.10. Follow up of a reported ADR/AEFI case: When an applicant is submitting a report and enters the same both date and Medical Report Number as a previous report, the reporting system shall warn the user that he needs to submit a follow up report.

3.11. Any missing/ needed information in the report will be requested through the system and the reporter shall provide it.

3.12. Any information related to the identity of the patient and/or the reporter of the ADR and AEFI will be fully protected as per the law and regulations.

3.13. DoH may provide the reporter/provider with recommendations to initiate further actions on the reported cases if necessary.

3.14. 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 .

3.15. Enquiries on ADR/ AEFI reporting can be directed to DoH pharmacovigilance program via Phone: 02-4191170/02-4191284, email: PVE@doh.gov.ae

4.Key stakeholder Roles and Responsibilities

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 and AEFI from the use of medical products to the Department of Health (DoH) Pharmacovigilance Section.

4.1.2. Must ensure that Healthcare Professionals are reporting ADR and AEFI and following policies and procedures.

4.1.3. Should assign a pharmacovigilance focal point. The focal point's responsibilities include:

4.1.3.1. Follow up with healthcare professionals within the facility for reporting ADR and AEFI and send any clarification to DoH when necessary.

4.1.3.2. Implement practices to improve the Pharmacovigilance reporting to DoH.

4.1.3.3. Educate healthcare professionals about the ADR and AEFI to the Pharmacovigilance program.

4.1.3.4. Receive reports on the reporting status of the facility.

4.1.3.5. Receive emails of alert/recall circulars and disseminate them to healthcare professionals and appropriate personnel within the facility.

4.1.3.6. Ensure necessary action is taken following an alert, recall, etc.

4.1.3.6. Become a member of Abu Dhabi pharmacovigilance network (ADPVN). This aims to ensure active participation in its activities and stimulate proactive reporting of all pharmacovigilance related incidents.

4.2. Healthcare professionals should:

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

4.2.2. Ensure documenting ADR / AEFI in the patient's medical record.

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

5.Monitoring and Evaluation

DoH will continuously evaluate the effectiveness, outcomes, and impact of this standard and where necessary adopt changes to ensure continuous improvements of ADRs and AEFI reporting system.

Healthcare providers shall ensure implementing monitoring and evaluating reporting system in their facilities and escalate any concerns or trends to DoH.

6.Enforcement and Sanctions

DoH -licensed Healthcare Providers and Healthcare Professionals must comply with the terms and requirements of this standard. DoH may impose sanctions in relation to any breach of requirements under this standard in accordance with the healthcare sector disciplinary regulation.

7. Relevant Reference Documents			
No.	**Reference Date**	**Reference Name**	**Relation Explanation / Coding / Publication Links**
1	Accessed May 2024	Chapter 40, Adverse Drug Reaction Reporting Side Effect Reporting Form	p4023-sample-chapter-40.ashx (ashp.org) https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada/adverse-reaction-reporting/consumer-side-effect-
2	Accessed May 2024	Serious AEFI, Interrater reliability of causality assessment for serious adverse events following immunization	https://www.who.int/groups/global-advisory-committee-on-vaccine-safety/topics/aefi/serious-aefi
3	Accessed May 2024	DoH Policies	https://www.DOH .gov.ae/en/resources/policies
4	Accessed May 2024	What is a Serious Adverse Event?	https://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm
5	Accessed May 2024	Introduction to Post-marketing Drug Safety Surveillance: Pharmacovigilance in FDA/CDER	https://www.fda.gov/media/96408/download
6	Accessed May 2024	CHAPTER XI. COMPLAINTS, INVESTIGATIONS, REGULATORY ACTION AND SANCTIONS	haad-regulator-manual-final-file_30dec12 (1).pdf