Document Type: Policy	**Ref No:** HRS/HPSD/ADRCV/1/2021	**Version Number:** 1
Document Title: Adverse Drug Reaction Reporting For COVID-19 Vaccine	**Effective Date:** 15/02/2021	**Revision Date:** 15/02/2024
Ownership: Drug Control Section-Clinical Audit and Control Department		
Applicability: All Health Facilities and Healthcare Professionals licensed under the jurisdiction of Dubai Health Authority.		

1. Purpose:

1.1. To align with the Dubai Health Authority (DHA) vision, mission and strategic objective, to direct resources to ensure healthy and safe environment for Dubai population.

1.2. To assure efficacy, safety and quality of all COVID-19 Vaccines in the Emirate of Dubai.

1.3. To introduce a unified tool for reporting Adverse Events Following Immunization (AEFI) with COVID-19 vaccine across all DHA licensed health facilities.

1.4. To define the responsibilities of all individuals involved in the adverse drug reaction (ADR) reporting process.

1.5. To provide a mechanism for identifying trends and subsequently introduce investigation and recommendations for improvement.

2. Scope:

2.1. Diagnosing and /or managing any adverse event or reaction following COVID-19 vaccination.

2.2. The process of identifying and reporting cases of Adverse Events Following Immunization (AEFI) with COVID-19 Vaccine.

3. Definitions and Abbreviations:

Adverse Reaction: Any unintended and unwanted effect or presentation that appears on the user of the medical product within the doses documented in the internal leaflet and the authorized uses within the marketing approval that occurs as a result of separate effects from those essential effects of the medical product.

A serious Adverse reaction: is one that requires inpatient hospitalization or prolongation of existing hospitalization, causes congenital malformation, result in persistent or significant disability or incapacity, is life threatening or result in death.

Health Facility: Any facility, owned and managed by natural or corporate body, provides medical services for individuals, including preventive, therapeutic and convalescent care services.

Healthcare Professional: is a natural person who is authorized and licensed by the DHA to practice any of the healthcare professions in the Emirate.

Medical Director: A DHA licensed physician who manages and runs a health facility and has clinical oversight of a DHA licensed health facility and its clinical staff.

Pharmacist in-charge: A qualified and trained DHA licensed pharmacist or clinical pharmacist assigned by the health facility as a pharmacy manager. The pharmacist in-charge shall be responsible and accountable for all the pharmaceutical practices in the pharmacy including the Narcotics, controlled and semi-controlled medications.

ADRs : Adverse Drug Reactions

AEFI: Adverse Event Following Immunization

DHA : Dubai Health Authority

HRS : Health Regulation Sector

MOHAP : Ministry of Health and Prevention

4. Policy Statement:

4.1. All health facilities administering COVID-19 vaccines or managing any AEFI shall develop and implement internal policy and procedure for reporting process for any side effect, unpredicted adverse effect or serious adverse event related to COVID-19 vaccines based on DHA rules and regulation , Ministry of Health and Prevention (MOHAP) ministerial decrees and UAE federal laws.

4.2. The health facility shall ensure the awareness of all healthcare staff on the ADR monitoring and reporting program.

4.3. The health facility shall implement an ongoing and concurrent surveillance system to identify potential AEFI.

4.4. Patient monitoring following Immunization for COVID-19 vaccines may include a collaborative approach between patient care providers, physicians, pharmacists, the patient and the family or caregivers.

4.5. Monitoring and assessing the potential side effect of the vaccine includes direct observation of the patient's physiological response to the vaccine administered and any problems or adverse effects associated with the vaccine.

4.6. Healthcare professionals should counsel the patient for any Adverse Drug Reactions (ADRs).

4.7. The DHA licensed treating physician must take full responsibility for any AEFI.

4.8. Physician/nursing staff/paramedical staff are responsible to report to the pharmacist/deputy in charge the identified AEFI.

4.9. Confidentiality of the ADR records shall be ensured by the responsible Healthcare professionals.

4.10. All reported AEFI should be evaluated and any required medical action shall be taken by the health facility.

4.11. The facility Medical Director will evaluate all data related to AEFI.

4.12. The health facility shall follow the below steps for reporting AEFI:

4.12.1. Health facilities with access to HASANA shall report through the platform.

a. Training to use the platform and report will be delivered by the HASANA team.

4.12.2. Health facilities that does not have access to HASANA, shall complete filing the ADR Reporting Form (**Appendix 1**).

4.12.3. Submit the form by the pharmacist in-charge or deputy in-charge via: AEFICOVID19@dha.gov.ae

a. AEFI of COVID-19 vaccines shall be reported within five (5) calendar days.

b. Serious adverse reactions, following COVID-19 vaccines shall be reported within forty eight (48) Hrs.

4.13. An advisory committee constituted at DHA will provide recommendations and may initiate further actions on the reported cases.

4.14. Based on the advisory committee recommendation, DHA will follow up with all the concerned parties and decide whether actions need to be taken in the light of the information obtained.

4.15. All health facilities and professionals are required to follow the UAE MOHAP Guidelines in Good Vigilance Practice (GVP) 2018 For Marketing Authorization Holders/Pharmaceutical Manufacturers in UAE, which includes the updated methods for reporting the side effects and

adverse reactions of medical products, which are registered, marketed, and used in public and private health institutions in the UAE.

4.16. For further information, contact DHA at: AEFICOVID19@dha.gov.ae

5. References

5.1. ASHP. January (2021). COVID-19 Vaccine Security, Storage, and Handling Resource Guide.

5.2. Dubai Health Authority (2013). Dubai Community Pharmacy Licensure and Pharmaceutical Practices Guideline. Available on: https://www.dha.gov.ae/Documents/Regulations/Dubai%20Community%20Pharmacy%20Licensure%20and%20Pharmaceutical%20Practices%20Guide.pdf (accessed 27 January 2021).

5.3. Federal Law No. (8) of (2019). Concerning Medical products, Pharmacy profession and Pharmacies.

5.4. Ministry of Health and Prevention Guidelines (2018). Concerning Good Vigilance Practice (GVP) For Marketing Authorization Holders / Pharmaceutical Manufacturers in UAE.

5.5. USP January (2021). Version 2.0. COVID-19 Vaccine Handling Toolkit: Operational Considerations for Healthcare Practitioners.

5.6. Zolezzi M. Parsotam N. The University of Auckland (2005), Adverse drug reaction reporting in New Zealand: implications for pharmacists.

6. Appendix

6.1. Appendix (1) Adverse Drug Reaction Reporting Form

Facility Details:

Facility name	
Facility ID	

Patient Details:

Full Name			
Emirates ID No.			
Hospital MRN No.			
DOB	**Age**	**Gender (M/F)**	**Nationality**

Vaccination Details:

Name of HCP who administered the vaccine	
Vaccination Date	
Product Name	
Lot Number(If applicable)	
Lot Expiry date(If applicable)	
Onset time interval (hours, days, weeks)	

Event Details:

Date of the adverse event reported (DD/MM/YYYY)	
Source of information for this event	☐ Client ☐ Guardian ☐ Healthcare Provider
Vaccine dose	☐ First dose ☐ Second dose
Presenting Symptoms	☐ Fever ☐ Fatigue ☐ Convulsion ☐ Skin reaction ☐ Headache ☐ Muscle ache ☐ Vomiting Cough ☐ Joint pain ☐ Diarrhea ☐ None
Local Reaction at or near injection site	☐ Redness ☐ Tenderness ☐ None ☐ Swelling ☐ Itching

Neurological events:	☐ Seizures	☐ Paresthesia
	☐ Quadriplegia	☐ Bell's Palsy
	☐ Meningitis	☐ Lower limb weakness
	☐ Stroke	☐ Paralysis Unspecified
	☐ Demyelination	☐ Numbness
	☐ Multiple Sclerosis	☐ Other Reaction
	☐ Encephalopathy/Encephalitis	☐ Hemiplegia
	☐ Fibromyalgia	☐ None
	☐ Guillain-Barre Syndrome (GBS)	
Presenting Reactions	☐ A neurovascular reaction (vasovagal syncope) that leads to fainting in an adolescent during/following vaccination	☐ Myocardial infarction
	☐ Severe allergic reaction (e.g. anaphylaxis)	☐ Right axillary lymphadenopathy
	☐ Hypersensitivity reactions	☐ Paroxysmal Ventricular Arrhythmia
	☐ Systemic Lupus Erythematosus	☐ Chest Pain
	☐ Vasculitis	☐ Short breath
	☐ Immune thrombocytopenia purpura (ITP)	☐ None of the above
	☐ Myocarditis	☐ Shoulder injury related to vaccination (SIRVA)
Other Reactions, Specify with details:		

Cause Code:	☐ A. Vaccine product related reaction ☐ B. Vaccine quality defect-related reaction ☐ C. Programmatic Error related reaction	☐ D. Immunization anxiety related reaction ☐ E. Coincidental event ☐ F. Inadequate Information to classify
Reaction Type	☐ Minor	☐ Serious or Severe
Initial Outcome	☐ Referred to other facility (emergency or hospital) ☐ Kept under short stay observation ☐ Hospitalization for observation or intervention ☐ ICU Hospitalization	
Final outcome	☐ Recovered ☐ Disability ☐ Died ☐ Discharged without full recovery, with outpatient follow up ☐ Discharged under home	
Management of the event		