Guidance for Healthcare Professionals - Reporting of Adverse Event Following Immunization of COVID-19 Vaccine (under Government COVID-19 Vaccination Programme)

Version 2.1

Drug Office

Department of Health

CONTENTS

1. Introduction

Adverse drug reaction reporting is an integral element in drug (including vaccine) safety surveillance and pharmacovigilance.

To enhance the post-authorization COVID-19 vaccine surveillance activities, the Drug Office of the Department of Health (DH DO) collects adverse event reports following immunization of COVID-19 vaccine in Hong Kong from healthcare professionals and conducts causality assessment to assist subsequent formulation of risk management strategies when necessary.

Healthcare professionals including doctors, Chinese medicine practitioners, dentists, pharmacists and nurses are encouraged to voluntarily report suspected adverse events of their patients after COVID-19 vaccination.

This document serves as a guidance for reporting adverse events following immunization under Government COVID-19 vaccination programme with vaccination date on or before 23 December 2023 only by healthcare professionals. It covers the types of adverse events which are encouraged to be reported, the information to be included in the report, and the manner of reporting.

2. What is Adverse Event Following Immunization?

2.1 Adverse Event following Immunization (AEFI)

An adverse event following immunization is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

2.2 Serious Adverse Event following Immunization

A serious adverse event following immunization is any untoward medical occurrence which follows immunization that:

- results in death
- is life-threatening
- requires in-patient hospitalization or prolongation of existing hospitalization
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect
- requires intervention to prevent one of the outcomes above (medically important).

2.3 Unexpected Adverse Event following Immunization

An unexpected adverse event following immunization is an adverse event following immunization whose nature, severity, specificity, or outcome is not consistent with the term or description used in the local product labelling.

3. How to Report?

Adverse event following immunization of COVID-19 vaccine can only be reported online via the COVID-19 Vaccine Adverse Event Online Reporting system at the weblink https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html

4. What to Report?

Healthcare professionals are encouraged to report the following adverse events following immunization under Government COVID-19 vaccination programme with vaccination date on or before 23 December 2023 only:

- all suspected serious adverse events, even if the adverse event is well known
- suspected drug interactions including vaccine-drug and vaccine-herb interactions
- non-serious adverse events but the adverse events are deemed medically significant by the healthcare professional (e.g. increased frequency or unusual presentation of a known adverse event)
- unexpected adverse events, i.e. the adverse events are not found in the product information or labelling (e.g. an unknown side effect)

According to World Health Organization (WHO), an Adverse Event of Special Interest (AESI) is a pre-identified and predefined medically-significant event that has the potential to be causally associated with a vaccine product that needs to be carefully monitored and confirmed by further special studies. The list of AESI adopted by the DH is available at the DO website (https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html).

If in doubt, please report.

You do not need to be certain that the adverse event is related to the COVID-19 vaccine.

5. What should be Included in the COVID-19 Vaccine Adverse Event Online Reporting?

Report separately online for each vaccine recipient. Please try to complete the online reporting to the best of your knowledge and provide as much information as possible. The following items are considered essential for causality assessment and tracing of individual vaccine recipient's vaccination record and should be provided whenever possible:

- vaccine recipient information (**full surname and initial of name** of the vaccine recipient, **full HKID card number or passport/travel document number, gender and date of birth** should be provided on the online report form)
- adverse event description (including the date of onset of adverse event and AEFI category*)
- drug therapy or vaccine including product name (particularly biological product and vaccine; or manufacturer's information) of the suspect drug and concomitant drug(s), batch number (particularly biological product and vaccine), dosage, route, dates of starting and stopping drug therapy, reason for use, etc.
- the interacting agent(s) (i.e. drugs, herbs or food) if suspected drug interaction is involved
- treatment of adverse event
- outcome of the adverse event
- sequelae of the adverse event
- comments (e.g. allergies, relevant information - hepatic and renal functions, alcohol use, smoking)
- reporter details (contact information should be provided for necessary follow-up; please read the Statement of Purposes (Appendix 1) in respect of the collection of personal data).

* Note: AEFI can be classified under one of the following Categories:

AEFI Categories	Descriptions
Allergic reactions	Anaphylaxis is the severe reaction that characteristically evolves rapidly towards cardiovascular collapse requiring resuscitative therapy. Other examples of severe allergic reactions are wheezing or shortness of breath due to bronchospasm, swelling of mouth or throat, skin manifestation (e.g. hives, eczema, pruritus); or facial or generalized edema. Allergic reactions usually occur within 24 hours of immunization.
Local reaction	Local reactions, usually occurs within 5 days of immunization, of concern may include abscess (sterile or infected), or other severe local reactions, such as redness and swelling that extend beyond the nearest joint or last 4 days or more.
Systemic reaction	Systemic reactions usually occur within 5 days of immunization but may occur later depending on the type of systemic reaction. Early onset ones of concern include toxic shock syndrome, hypotonic-hyporesponsive episode, persistent crying or screaming episodes, high fever (greater than 39 ^{o}C or 102.2 ^{o}F), sepsis, or rash (especially those lasts for 4 days or more or requires hospitalization). Thrombocytopaenia (with platelet < 50,000/mm^3) may have a delayed onset.
Neurological disorders	Some neurological adverse reactions may be related to vaccination. Bell's palsy, encephalomyelitis, encephalopathy, Guillain-Barré Syndrome or transverse myelitis, if occurred within 42 days of immunization, may be related to the immunization.

5.1 Follow-up Reports

Acknowledgement email with a unique case reference number will be issued within several days after each COVID-19 vaccine adverse event report received. Any follow-up information of a COVID-19 vaccine adverse event report that has been submitted to DH DO previously can be supplemented using the COVID-19 Vaccine Adverse Event Online Reporting system via the weblink https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html again. Please indicate that it is a follow-up report and quote the unique case reference number from the previous report.

6. How to Report?

Report online using the COVID-19 Vaccine Adverse Event Online Reporting system via the weblink https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html and then submit online.

7. What Happen to the Report?

Any information related to the identities of the reporter and the vaccine recipient will be kept in strict confidence.

All adverse event reports of COVID-19 vaccine are reviewed by a team of professional staff. Serious adverse event reports of COVID-19 vaccine may be reviewed by the Expert Committee on Clinical Events following COVID-19 immunization.

Information of the report will be entered into the COVID-19 Vaccine Adverse Event database system for analysis.

Through monitoring and analysis of adverse event reports of COVID-19 vaccine, signals related to safety profile of COVID-19 vaccines such as unexpected adverse events, unusual presentation of a known adverse event, or a susceptible patient group may be identified. These findings will initiate further evaluation to establish the potential of COVID-19 vaccine in causing the adverse event and provide important information for the DH DO to initiate necessary actions such as changes in marketing authorization or providing early warnings to healthcare professionals.

8. Contact for Further Information

Clinical Trials and Pharmacovigilance Unit
Drug Office, Department of Health
Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong, Kowloon, Hong Kong
Phone: 2319 2920
Fax: 2319 6319
Email: adr@dh.gov.hk

Appendix 1 Statement of Purposes

Purpose of Collection

This personal data are provided by reporter for the purposes of reporting adverse event following immunization of the vaccine recipient to the Department of Health (DH). The personal data provided will be used by DH for the following purposes:

(a) follow-up of the case report; and

(b) surveillance of drug-related events.

2. The provision of personal data is voluntary. If you do not provide sufficient information, we may not be able to assess the report properly.

Classes of Transferees

3. The personal data you provide are mainly for use within DH. Apart from this, the data may only be disclosed to parties where you have given consent to such disclosure or where such disclosure is allowed under the Personal Data (Privacy) Ordinance.

Access to Personal Data

4. You have a right of access and correction with respect to personal data as provided for in sections 18 and 22 and Principle 6 of Schedule 1 of the Personal Data (Privacy) Ordinance. Your right of access includes the right to obtain a copy of your personal data. A fee may be imposed for complying with a data access request.

Enquiries

5. Enquiries concerning the personal data provided, including the making access and corrections, should be addressed to:

Senior Pharmacist
Clinical Trials and Pharmacovigilance Unit
Drug Office
Department of Health
Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East,
100 How Ming Street, Kwun Tong, Kowloon, Hong Kong
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Document Information

Version	Date	Description of Change
1.0	February 2021	(First Version)
1.1	June 2021	• Updates contact information
2.0	March 2022	• Updates AEFI Categories Descriptions
2.1	January 2024	• Updates contact information, scope of AEFI reporting and document title

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