Guidance for Pharmaceutical Industry - Reporting Requirements 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

1.1 Purpose

This guidance sets out the requirements for reporting adverse events following immunization of COVID-19 vaccine[1] under Government COVID-19 vaccination programme with vaccination date on or before 23 December 2023 only to the Department of Health Drug Office ("DH DO") by pharmaceutical industry. It covers the types of adverse events which should be reported, and the timelines and other requirements for reporting adverse events following immunization of COVID-19 vaccine.

1.2 Scope

This guidance applies to the reporting of adverse events following immunization of COVID-19 vaccine in Hong Kong by pharmaceutical industry.

Pharmaceutical industry in this guidance includes:

- Authorization applicants of COVID-19 vaccine under the Prevention and Control of Disease (Use of Vaccines) Regulation (Cap. 599K)
- the holders of Certificate of Drug/Product Registration ("Registration Certificate Holders") of COVID-19 vaccine
- the holders of Certificate for Clinical Trial/Medicinal Test ("Clinical Trial Certificate Holders") of COVID-19 vaccine

Pharmaceutical industry should comply with the requirements set out in this guidance.

[1] "COVID-19 vaccine" refers to "Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccine"

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. What Report Format should be Used?

For reporting of adverse events following immunization of COVID-19 vaccine (i.e. COVID-19 vaccine as a suspect drug or one of the suspect drugs), the report should be submitted online using the COVID-19 Vaccine Adverse Event Online Reporting system via the weblink https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/adr_reporting/index.html only.

4. What should be included in the COVID-19 Vaccine Adverse Event Online Reporting?

The online reporting should be completed to the best of knowledge and information should be provided as much 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.

4.1 Follow-up Report

Any follow-up information of a COVID-19 vaccine adverse event that has been reported to DH DO previously should be submitted online using the COVID-19 Vaccine Adverse Event Online Reporting system again via the weblink https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/adr_reporting/index.html only. Please quote the unique case reference number assigned to the previous adverse event report when reporting online via the weblink.

5. What and How to Report?

5.1 Local COVID-19 Vaccine Adverse Event Reporting

5.1.1 Local Serious COVID-19 Vaccine Adverse Event

Pharmaceutical industry should report all serious or unexpected adverse event following immunization of COVID-19 vaccine occurring in Hong Kong under Government COVID-19 vaccination programme with vaccination date on or before 23 December 2023 only to DH DO

as soon as possible and no later than 15 calendar days of receipt of information. Follow-up reports should also be submitted as required.

For other reporting requirements as the conditions for registration approval and conditions attached to the authorization, Registration Certificate Holders and Authorization applicants of COVID-19 vaccines should refer to the conditions specified on the Certificate of Drug/Product Registration and conditions attached to the authorization for details.

5.1.2 How to Report

For local COVID-19 vaccine adverse event reporting (i.e. COVID-19 vaccine as a suspect drug or one of the suspect drugs), the report should be submitted online using the COVID-19 Vaccine Adverse Event Online Reporting system via the weblink https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/adr_reporting/index.html only.

If the adverse events are related to the COVID-19 vaccine used in clinical trial, please refer to sections 5.2 of this guidance. Pharmaceutical industry may refer to the table summarizing those scenarios at Appendix 2 of this guidance for easy reference.

5.2 COVID-19 Vaccine Used in Clinical Trials

5.2.1 Adverse Events Following Immunization

Clinical Trial Certificate Holders should report all local adverse events following immunization of COVID-19 vaccine that are serious and unexpected as soon as possible to Clinical Trials and Pharmacovigilance Unit of DH DO.

Fatal or life-threatening unexpected adverse events of COVID-19 vaccine should be reported as soon as possible but no later than 7 calendar days after first knowledge by the sponsor that a case qualifies, followed by a report as complete as possible within 8 additional calendar days. This report must include an assessment of the importance and implication of the findings, including relevant previous experience with the same or similar pharmaceutical products.

Other serious, unexpected adverse events of COVID-19 vaccine that are not fatal or life-threatening, it should be reported as soon as possible but no later than 15 calendar days after first knowledge by the sponsor that the case meets the minimum criteria for expedited reporting.

For non-serious adverse events and serious adverse events of COVID-19 vaccine that are expected, it should be reported in a brief summary at the conclusion of the trial to Clinical Trials and Pharmacovigilance Unit of DH DO.

5.2.2 How to Report

Clinical Trial Certificate Holders should submit serious and unexpected adverse event report of COVID-19 vaccine (i.e. COVID-19 vaccine as a suspect drug or one of the suspect drugs) (under Government COVID-19 vaccination programme with vaccination date on or before 23 December 2023 only) online using the COVID-19 Vaccine Adverse Event Online Reporting system via the weblink https://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/adr_reporting/index.html only.

Clinical Trial Certificate Holders should submit the brief summary at the conclusion of the trial to the Clinical Trials and Pharmacovigilance Unit of DH DO by email to ct@dh.gov.hk or by

post to the Clinical Trials and Pharmacovigilance Unit at Suite 2002-05, 20/F, AIA Kowloon Tower, Landmark East, 100 How Ming Street, Kwun Tong, Kowloon, Hong Kong.

For more details concerning safety reporting related to clinical trial, please refer to the "Notice of requirement on reporting of local drug related safety report, progress report and final study report in clinical trial" available at http://www.drugoffice.gov.hk/eps/do/en/pharmaceutical_trade/guidelines_forms/clinicalTrial.html.

6. Contact 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

For enquiries on reporting adverse drug reaction:
Phone: 2319 2920
Fax: 2319 6319
Email: adr@dh.gov.hk

For enquiries from Clinical Trial Certificate Holders:
Phone: 3974 4180
Fax: 2803 4962
Email: ct@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
Tel: 2319 2920

Appendix 2 Summary of COVID-19 Vaccine Adverse Event Reporting Requirements

Who to Report	Type of Adverse Event Report	Type of Pharmaceutical Product	Reporting Time-frame	Reporting Office
Authorization applicants of COVID-19 vaccine, Registration Certificate Holders of COVID-19 vaccine	Local serious or unexpected adverse event^	COVID-19 vaccine excluding those used in clinical trials	As soon as possible and no later than 15 calendar days	Clinical Trials and Pharmacovigilance Unit, Drug Office, Department of Health
Clinical Trial Certificate Holders of COVID-19 vaccine	Fatal or life-threatening unexpected adverse Event	COVID-19 vaccine used in clinical trials	As soon as possible and no later than 7 calendar days, followed by a report as complete as possible within 8 additional calendar days	
	Other serious and unexpected adverse event		As soon as possible and no later than 15 calendar days	
	Non-serious adverse event / Serious expected adverse event		At the conclusion of the trial (reported in brief summary)	

^Additional reporting requirements may be specified on the Certificate of Drug/Product Registration and conditions attached to the authorization.

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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