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SPECIAL ADMINISTRATIVE REGION
DRUG OFFICE
DEPARTMENT OF HEALTH
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Dear Healthcare Professionals,

Reporting of Adverse Event following Immunization (AEFI) of COVID-19 Vaccine

I am writing to appeal to you to report suspected AEFI of COVID-19 vaccine to the Drug Information and Pharmacovigilance Division of the Drug Office, Department of Health (DH).

As we all know that COVID-19 vaccine is one of the critical interventions against COVID-19 pandemic, the unprecedented rapid development of the COVID-19 vaccines on novel platforms followed by its rapid deployment on a mass scale poses unique challenges in monitoring vaccine safety. Timely reporting of adverse events following COVID-19 immunization is the first step in ensuring the continued safety of the vaccine. The Government has procured COVID-19 vaccines to serve the whole of the Hong Kong population and would arrange for members of the public to receive vaccination as early as possible under the set priority. It is very important that report of AEFI can provide vital information for monitoring the safety of the vaccine. Therefore, your proactive support in identifying the association between AEFI and the vaccine, and timely report to us via the dedicated COVID-19 Vaccine Adverse Event Online Reporting system at (https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html) shall make contribution to the success of immunization programs.

Some common minor reactions after vaccinations such as minor local reactions and low-grade fever are not required to be reported. Nevertheless, you are encouraged to report AEFIs if they are doubtful of the relationship or clinically significance between the vaccine and the AEFI concerned. Additional information on the reporting of COVID-19 Vaccine Adverse Event can be found in our guidance at the above mentioned website.

Please refer to the attached Annex for a summary guidance of Reporting of AEFI of COVID-19 vaccines. You may also wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,

(WY CHOW)
for Assistant Director (Drug)

We build a healthy Hong Kong and
aspire to be an internationally renowned public health authority

Reporting of ADVERSE EVENT FOLLOWING IMMUNIZATION (AEFI) of COVID-19 VACCINES for Healthcare Professionals

DO YOUR PART TO MONITOR COVID-19 VACCINES' ADVERSE EVENTS !

1

Monitor whether a patient experienced an adverse event after COVID-19 vaccination.

2

Report adverse events to the Drug Office of the Department of Health using COVID-19 Vaccine Adverse Event Online Reporting system.

3

Contact Drug Office of the Department of Health if you have any questions about AEFI reporting at 2319 2920.

QUESTIONS & ANSWERS

What is an AEFI?

An adverse event following immunization (AEFI) is any untoward medical occurrence which follows immunization and which does not necessarily have a causal relationship with the usage of the vaccine.

What is an AESI?

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.

What types of adverse events should be reported?

You should report any event which may be related to vaccine. Of particular importance are events which are serious, or unusual or unexpected events. Submitting a report does not mean that the vaccine caused the event.

Why is it important to report an AEFI?

When you report an AEFI you provide vital information that is needed to monitor vaccine safety. This information is also used to report on vaccine safety to the public, which contributes to the success of COVID-19 immunization program.

What does NOT need to be reported?

Some common or mild events do not need to be reported. These include: low-grade fever or minor local reactions.

Who should report an AEFI?

Healthcare professionals (e.g. physicians, nurses and pharmacists) are encouraged to voluntarily report AEFIs. Reports should be made using the COVID-19 Vaccine Adverse Event Online Reporting system.

If in doubt, please report.

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

The COVID-19 Vaccine Adverse Event Online Reporting system, the list of AESI adopted by the Department of Health, and the Guidance for Healthcare Professionals - Reporting of Adverse Event Following Immunization of COVID-19 Vaccine are all available at: https://www.drugoffice.gov.hk/eps/do/en/healthcare_providers/adr_reporting/index.html