Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

FDA ADVISORY
No. 2021-2290

10 SEP 2021

TO: **ALL HEALTHCARE PROVIDERS AND THE GENERAL PUBLIC**

SUBJECT: **Reporting of Adverse Reactions to Drugs and Vaccines**

The Food and Drug Administration (FDA) reminds healthcare providers, consumers, and patients to report adverse reactions to drugs and vaccines to the FDA- National Pharmacovigilance Center especially during this time of the COVID-19 Public Health Emergency, in order to monitor the safety of the product and identify possible health problems.

As per Department of Health Administrative Order No. 2011-0009 entitled "National Policy and Program on Pharmacovigilance" Section VII, D. states that, *"Healthcare professionals are required to report to the FDA any suspected adverse event arising from the use of pharmaceutical products..."* Thru this AO, all hospitals are also expected to activate their Pharmacovigilance Unit which are responsible in collecting and evaluating the data. Further, this policy also enjoins the patients and consuming public to report any adverse events following intake of drugs and immunization of vaccines.

Adverse events or reactions are unintended occurrences following use of drugs or vaccines. All medicines have the potential to cause side effects and health problems especially if not used properly. Similarly, all vaccines are expected to have cases of breakthrough infections. For COVID-19 breakthrough infection, it is defined by the US-Center for Disease Control and Prevention as *"the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person ≥14 days after they have completed all recommended doses"*. These events may also be reported to the FDA.

Hence, the FDA encourages healthcare providers, consumers, and patients to report suspected adverse reactions from drugs or adverse events following immunization of currently registered FDA medicines and vaccines as well as all COVID-19 vaccines authorized for emergency use. The collected data shall be valuable in assessing medication safety as part of the monitoring and surveillance. This plays an important role in achieving the desired patient outcomes and address the management of these events.

Report any adverse reactions to drugs and vaccines via online reporting through the FDA website or through the hospital's respective VigiFlow accounts, the national database system for collection and processing of individual case reports and data.

For more information and inquiries, kindly contact the Pharmacovigilance Section at 8809-5596 or email pharmacovigilance@fda.gov.ph.

For dissemination to all concerned.

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