



DEPARTMENT OF HEALTH
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TO : All CEOs of Provincial Health Authorities & Hospitals
: EPI Program Managers (National, Provincial & District)
: COVID-19 Vaccination Site Managers/Officer In-Charges & Vaccinators
: All Managers of Private Health Hospitals & Clinics
: All Healthcare Professionals

Date : Tuesday 17th August 2021

File Ref. No. : PSS – 7-1: PHARMACOVIGILANCE: COVID-19 VACCINES SAFETY SURVEILLANCE

SUBJECT : MANDATORY REPORTING OF ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) FOR COVID-19 VACCINES & REPORTS TO BE COMMUNICATED TO THE NATIONAL PHARMACOVIGILANCE CENTRE AT THE PHARMACEUTICAL SERVICES STANDARDS BRANCH, NATIONAL DEPARTMENT OF HEALTH

This Circular Serves to inform you all in relation to the above international mandatory obligation to be proactive in the COVID-19 Vaccines Safety Surveillance during this time of rolling out mass immunization in larger selected age groups globally. This is due to the continuous rapid global surge in novel coronavirus, SARS-CoV-2 (COVID-19) infection which has already caused the loss of more than 4.5 million lives and thus this has triggered the swift deployment of large volumes of COVID-19 vaccines doses in many countries including Papua New Guinea.

As a response to contain the pandemic, global collaboration has been established and that converges all governments, scientists, businesses, civil society, and philanthropists and global health organizations to accelerate at unprecedented efforts using different platforms in the development, production, and equitable access to COVID-19 diagnostic tests, treatments, and vaccines. In extending this collaborative global convergence to PNG local context, **the 42nd Global Advisory Committee on Vaccine Safety** has addressed Pharmacovigilance preparedness by COVID-19 Vaccine recipient countries and recommends that **Mandatory Surveillance for Adverse Events Following Immunization (AEFI)** is an integral part of the Immunization and Vaccine Development Program, and reinforces the safe use of all vaccines in the country while also helping to maintain public confidence in its immunization program.

Please be informed that all COVID-19 vaccines have not been given full **Marketing Authorization** approvals by stringent International Drug Regulatory Authorities but enlisted for **Emergency Use Authorization** only based on short-term safety data available at this time of use; besides their long-term safety, risk versus benefit and efficacious profiles are still being studied while they are used for mass immunization to selected age groups globally.

Therefore, as an international obligatory collaboration, the National Department of Health urgently requests that all healthcare workers and stakeholders in Papua New Guinea to be proactive in COVID-19 Vaccines Safety Surveillance. All AEFIs (including non-serious and serious) cases must be reported using an **AEFI Reporting Form** within 24 hours of notification and forwarded to the **National Pharmacovigilance & Drug Information Centre** at the Pharmaceutical Services Standards Branch, (NDoH).

For further information and enquires regarding the COVID-19 Vaccines Safety Surveillance and AEFI reporting, please contact **Mr. Ronald Y. Jorim, Pharmacovigilance & Drug Information Officer** on Telephone (+675) 301 3886 or on email pngdipu@gmail.com

Thank you for your stringent vigilance and immediate collaborative action in this agenda.

DR. OSBORNE LIKO
Secretary for Health

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