TERMS OF REFERENCE

PHARMACOVIGILANCE OFFICER
SURVEILLANCE OF ADVERSE DRUG REACTIONS
DUE TO COVID-19 VACCINES

March 2, 2022 to September 30, 2022

1. BACKGROUND

On 30 January 2020, the World Health Organization (WHO) declared the outbreak of COVID -19 a Public Health Emergency of International Concern. By 12 March 2020, due to its rapid global spread, the outbreak was declared a pandemic.

An essential strategy in controlling this pandemic is the rapid development of safe and effective vaccines. In this context, the surveillance systems of the countries of the Americas must be prepared to detect and report, in a timely manner, all Events Supposedly Attributable to Vaccine or Immunization (ESAVI). In addition, there is a list of Adverse Events of Special Interest (AESI), which is continuously updated by WHO's Global Advisory Committee on Vaccine Safety (GACVS). These events should be monitored through surveillance, according to the guidelines set forth in the WHO Global Manual on Surveillance of Adverse Events Following Immunization (1). The GACVS is harmonizing the AESI list with the criteria of the Brighton Collaboration (BC), whose list is updated with the appearance of new ESAVI and AESI, for which case definitions are then formulated (2).

The Pan American Health Organization/World Health Organization (PAHO/WHO) issued its Guidance for Implementing the Regional COVID-19 Vaccine ESAVI/AESI Surveillance System, which includes ten recommendations to strengthen national ESAVI surveillance capacities. One of the specific objectives of this system is to "design and implement COVID-19 vaccine safety surveillance through intensified passive surveillance, active sentinel surveillance, and epidemiological studies" (3).

The Standards and Regulation Division of the Ministry of Health and Wellness has responsibility for the maintenance of an effective regulatory framework for the regulation of pharmaceuticals, biologicals, nutritional products, herbal products, medical devices, cosmetics, chemicals and diagnostic agents. The mandate of the Branch is to ensure the safety, efficacy and quality of products available on the Jamaican market through the effective drug registration and monitoring and import permit approval system. These functions are executed through the Permit Approval and Product Registration Units. The PRAB has the responsibility for administering a post marketing surveillance programme for monitoring the safety and effectiveness of approved products (medicines, vaccines, etc), detecting unapproved falsified, substandard and harmful products on the market, and taking the appropriate regulatory actions to safeguard the public.

Since the the introduction COVID-19 vaccines in Jamaica, there has been a 633% increase in adverse drug reaction (ADR) related to COVID-19 vaccines. There is need to strengthen the current pharmacovigilance programme to allow for the robust monitoring system required for the vaccines which are still in the Phase III clinical study phase and for which missing information must be documented and reports generated to add to the body of knowledge and to manage risks.

2. OBJECTIVE OF THE CONSULTANCY

The objective of the consultancy is to support the PRAB in the monitoring of adverse drug reaction activities due to COVID-19 vaccines in Jamaica.

3. SCOPE OF WORK

- Review ADR reports for completeness and accuracy of information and take the necessary action.
- Acknowledge receipt of reports and inform client of the way forward.
- Code, enter, and prepare ADR data for analysis based on established standard.
- Support the piloting of the transfer of a copy of the database of Events Supposedly Attributable to Vaccination or Immunization (ESAVI) without any edits to the PAHO Immunization Regional Database.
- Support the piloting the implementation of an electronic information system to capture ESAVI/AESI case-based data, to transfer to a national database for a systematic analysis of ESAVI.
- Facilitate training and sensitization in ADR reporting.

4. SPECIFIC ACTIVTIES

- Receive and acknowledge submission of ADR reports.
- Review ADR reports for accuracy and completeness.
- Take the necessary corrective action by contacting and liaising with clinicians, health facility staff, parish health department staff, regional health authority staff, and where necessary, patients, to complete ADR reports.
- Enter ADR data in established databases base on established protocol.
- Review ADR databases for completeness.
- Liaise with Health Services Planning and Integration Branch, Family Health Unit, staff to cross-validate data on reports.
- Provide support to field staff through continued training and sensitization on ADR reporting and be available to answer questions, solve problems.
- Provide support to assess baseline and progress performance of the COVID-19 Vaccination ADR Reporting System.
- Assist with preparing daily, weekly and ad hoc ADR Reports as needed.
- Support the piloting of the transfer of a copy of the database of Events Supposedly Attributable to Vaccination or Immunization (ESAVI) without any edits to the PAHO Immunization Regional Database.
- Support the piloting the implementation of an electronic information system to capture ESAVI/AESI case-based data, to transfer to a national database for a systematic analysis of ESAVI.

- Any other relevant duties as deemed fit.

5. REQUIREMENTS OF CONSULTANT

The preferred candidate should meet the following criteria:

- Bachelor of Pharmacy Degree from a recognized institution.
- Two (2) years' experience as a pharmacist, to include internship.
- Registered Pharmacist with the Pharmacy Council of Jamaica.
- Knowledge of the National Health Policies.
- Intermediate proficiency in Microsoft Office.
- Good interpersonal skills and ability to work independently as well as within interdisciplinary teams.
- Demonstrated evidence of skills in critical analysis of quantitative data and good report writing.
- Experience in managing databases and ability to use various online platforms and mobile applications

6. DELIVERABLES

	Deliverable	**Date Due**
1.	Monthly report on ADR relating to COVID-19 vaccines and status of data transfer of ESAVI data to PAHO Immunization Regional Database	March 24,2022
2.	Monthly report on ADR relating to COVID-19 vaccines and status of data transfer of ESAVI data to PAHO Immunization Regional Database ADR training and sensitization plan for field staff	April 24,2022
3.	Monthly report on ADR relating to COVID-19 vaccines and status of data transfer of ESAVI data to PAHO Immunization Regional Database.	May 24,2022
4.	Monthly report on ADR relating to COVID-19 vaccines and status of data transfer of ESAVI data to PAHO Immunization Regional Database Status of ADR training and sensitization of field staff	June 24, 2022
5.	Monthly report on ADR relating to COVID-19 vaccines and status of data transfer of ESAVI data to PAHO Immunization Regional Database	July 24,2022
6.	Monthly report on ADR relating to COVID-19 vaccines and status of data transfer of ESAVI data to PAHO Immunization Regional Database	August 24, 2022

7.	Monthly report on ADR relating to COVID-19 vaccines and status of data transfer of ESAVI data to PAHO Immunization Regional Database	September 24, 2022
	Total	

The consultancy will be for the period March 2, 2022 to September 30, 2022

7. REMUNERNATION

The consultant will be remunerated as per PAHO Salary Scale. The consultant is required to submit each deliverable and an invoice for payment as per the schedule set out in Section 6. The deliverable will be reviewed by the supervising officer (s) and once it is approved, the consultant will be paid the agreed amount.

8. REPORTING RELATIONSHIP

The consultant reports directly to the Advisor, Non-Communicable Diseases and Public Health and Focal Point for Immunization and Family, Health Promotion and Life Course in the PAHO Jamaica Office, through the Director of Standards and Regulation in the Ministry of Health and Wellness. The consultant will also work collaboratively with the PAHO Consultant Epidemiologist and the National PAHO Consultant for Immunization.

9. EVALUATION CRITERIA

Criteria	**Maximum Score**
Qualifications as evidenced by the CV presented	25
Specific knowledge of surveillance of ADR	25
Evidence of skills in critical analysis of quantitative data	25
Evidence of success working in interdisciplinary teams	25

ESSENTIAL REFERENCE DOCUMENTS

1. World Health Organization. COVID-19 Vaccines: Safety Surveillance Manual. Available at: https://www.who.int/publications/i/item/10665206144. Accessed 2/1/2021.
2. Brighton Collaboration. Taken from: https://brightoncollaboration.us/covid-19/. Accessed 2/6/2021.
3. Pan American Health Organization. Guidance for Implementing the Regional COVID-19 Vaccine AEFI/AESI Surveillance System. Taken from: https://iris.paho.org/handle/10665.2/53340, accessed 6/1/2021.