1. **Summary**

The World Health Organization (WHO) Philippines is looking for an institution contractual partner for strengthening Vaccine Pharmacovigilance through training workshop. The proposals are due by 30 January 2019.

2. **Background**

The World Health Organization (WHO) defines pharmacovigilance as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. Therefore pharmacovigilance is one of the important tools in pre-marketing /pre-clinical monitoring of adverse drug reactions and post-marketing surveillance by ensuring the safety of pharmaceutical and related health products.

This activity will cover the overview of pharmacovigilance challenges and implementation, identification of roles and responsibilities (Distributor, National Regulatory Authority (also known as the Philippine Food and Drug Administration), Department of Health (DOH) ), regulation and post marketing surveillance. With this, the NRA and the DOH will increase their capacity in the effective management and implementation of Pre and Post Marketing Surveillance.

The selected partner will work together with counterparts and development partners under the supervision of WHO Country Office to carry out the following activities: a). Prepare training program and design modules to capacitate team players in vaccine pharmacovigilance through specific seminars/workshop and b). Provide recommendations on how to improve PFDA and DOH strengthen its capacity in vaccine pharmacovigilance.

3. **Timeline**

The implementation timeline for the project is from February 2019 to March 2019.

4. **Place of Assignment**

Manila, Philippines

5. **Scope of Work**

In coordination with WHO Philippines and the Department of Health, the selected contractual partner shall deliver the following:

**Output 1**: The design and logistical arrangements for the offsite workshop

- **Deliverable 1.1**: Implementation of the workshop, including venue, accommodation, and transport arrangements
- **Deliverable 1.2**: Training modules that include presentation slides and evaluation tools on the following topics:
Introduction to Vaccine Safety - Importance of immunization programs, history of vaccine development, how vaccine work, vaccine-preventable diseases, types of vaccine

Vaccine and Drugs: similarities and differences- Similarities of drug and vaccines, differences between drug and vaccines

Vaccine Pharmacovigilance-Introduction, Regulation of vaccines, role of EPIs and NRA in vaccine pharmacovigilance, how to set-up vaccine pharmacovigilance system, national AEFI technical advisory committee

Adverse Events Following Immunization- Introduction and overview, types of AEFIs, vaccination failure, case definitions for AEFI, investigating AEFI, causality assessment of AEFIs

Signal Identification- Definition of signals in vaccine pharmacovigilance, signal detection, signal communication, strengthening the signal, actions to take following signal identification

Communication, Crisis Management and Media Relations- Introduction to communication, principles of effective communication, crisis management, media relations, developing communication and crisis management resources

**Output 2:** Conduct series of lectures following international Vaccine Pharmacovigilance principles, NRA roles and responsibilities in the regulation of vaccine safety, NIP roles and responsibilities in the management of AEFIs, ADR and AEFI surveillance

- Deliverable 2.1: Training-of-trainers workshop on the topics identified on deliverable (3 days)

**Output 3:** Final Activity Report with recommendations addressed to Philippine FDA Director General as well as the Deputy Director General for Field Regulatory Operations, Director IV of the Center for Drug Regulation and Research and representatives from the DOH Epidemiology Bureau and Pharmaceutical Division (PD)

6. **Qualifications**
The contractual partner must fulfil the following qualifications:

**Education and Certifications**
- Essential: Postgraduate degree in Pharmacy, or Public Health or any other related field in pharmacovigilance and Pharmacoepidemiology
- Desirable: Doctorate Degree or undergoing further studies in Medicine, Pharmacy or any related to Pharmacoepidemiology and pharmacovigilance

**Work Experience**
- Experience with pharmacovigilance practice particularly in AEFI
- Background on immunization program is desirable

**Technical Skills and Knowledge**
- Must be part of the AEFI processing and investigation, signal detection and communication
**Language Fluency:**
- Expert fluency in English

In addition, the contractual partner must have no direct or indirect interest in the tobacco industry, alcohol industry, arms dealing or human trafficking.

7. **Other Requirements**
The expert/trainor is expected to travel according to the itinerary based on the proposed activity plan.

8. **Submission Requirements**
Interested institutions and/or individuals should submit electronic copies of the following:
- Cover letter
- Proposal with financial details and proposed timeline
- Company profile and qualifications of team members (if institution) or curriculum vitae (if individual)

Address all proposals to:

**Dr Gundo Weiler**
WHO Representative in the Philippines
Ground Floor, Building 3, Department of Health San Lazaro Compound
Rizal Avenue, Sta Cruz, Manila

Please submit the electronic copy of the proposals with the title Technical Assistance for Strengthening Vaccine Pharmacovigilance through Training to Ms. Ghenimelle Pasumbal (pasumbalg@who.int), Ms. Pao Hernandez (phernandez@who.int), and wpphlwr@who.int. Only shortlisted applicants will be contacted by WHO Philippines.

Deadline of submission of proposals is on **30 January 2019**.