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**World Health
Organization**

Sri Lanka

VACANCY NOTICE



The Mission of WHO is the attainment by all peoples of the highest possible level of health

Vacancy Notice No: WCO-SRL-2020/02

Date: 15 June 2020

Title: National Consultant

**Support to strengthen the monitoring and
evaluation of the regulatory functions of the
National Medicines Regulatory Authority**

Deadline for application : 25 June 2020

Contract type: Special Services Agreement

Grade: NO-C

Duration of contract: 12 months

Organization unit: Country Office for Sri Lanka

Introduction:

Quality-assured, safe and effective medicines, vaccines and medical devices are fundamental to a functioning health system. But globalized trade can undermine regulation, and in resource-limited settings especially, incidence of substandard or falsified medicines is growing. WHO aids countries to strengthen regulation, including post-marketing surveillance, and to eliminate substandard and falsified medicines. It also develops international norms and standards, so that countries worldwide can regulate health products and technologies consistently.

As part of the support of the WHO to strengthen the regulatory capacity of the National Medicines Regulatory Authority (NMRA) of Sri Lanka, in November 2019, the Sri Lankan medicines regulatory body was assessed using the Global Benchmarking tool with identification of an Institutional Development Plan with 299 recommended activities to be fulfilled to reach the recommended maturity level 3. Recommendations include monitoring and evaluation actions to improve the quality of regulatory functions, improve quality of GMP inspections, strengthen pharmacovigilance and market surveillance and to build the capacity of regulators.

It is in this background that WCO-SRL is seeking the services of a Consultant to technically support the strengthening of the monitoring and evaluation of the regulatory functions of the National Medicines Regulatory Authority of Sri Lanka.

Objectives of the Consultancy:

To strengthen the monitoring and evaluation of the regulatory functions of the National Medicines

Job Description:

The national consultant is expected to;

- Design a system for audits and conduct periodic audits and reviews to improve overall quality of regulatory functions of the staff
- Design checklists, report formats and feedback forms to improve quality of (i) GMP inspections, both local and overseas (ii) registration dossier evaluations
- Design a mechanism to ensure uniform implementation of policies and harmonization of regulatory actions/decisions of regulatory pharmacists.
- Improve regulatory oversight provided to special molecules (e.g. biosimilars, blood products).
- Conduct identified trainings to improve knowledge of regulatory staff
- Establish a pharmacovigilance system and training of regulatory staff of NMRA on pharmacovigilance activities
- Provide guidance to medicine manufacturers, importers and distributors to establish pharmacovigilance systems in their organizations
- Contribute to the work of WCO on improving access to essential medicines vaccines, diagnostics and devices on primary health care and other related technical work at WHO Country office Sri Lanka.
- Any other work assigned by the supervisor

Recruitment Profile:

Education:

Essential

- PhD/ MD in the field of Clinical Pharmacology

Desirable:

- Training on pharma regulations

Experience:

Essential

- At least 10 years work experience in clinical pharmacology and regulations
- Demonstrate experience and capacity on medicines regulation as evidenced by applicants work in this area
- Experience in formulating monitoring and evaluating tools, collecting and analysis of data for decision making

Desirable

- International work experience in the areas of essential medicines and medicines regulations

Language Skills:

- Excellent written and spoken English, fluency in Sinhala or Tamil.

Competencies:

- Producing results
- Teamwork
- Respecting and promoting individual and cultural differences
- Communicating in a credible and effective way
- Ensuring effective use of resources

Annual Salary & others Benefits:

Annual Salary

- Annual salary will be based on WHO local salaries for National Professional Staff

Others Benefits

WHO Offers locally competitive packages such as:

- Health Insurance; Accident and illness insurance;
- Annual Leave (30 days per year)
- Sick leave (7 days per year);
- WHO Holidays

Special Requirement

- Availability to start work in two weeks of selection

NOTE:

- 1) Qualified Candidates will be evaluated and interviewed.
- 2) Applicants should send a brief **Resume** of their relevant experience, explaining reasons for being suitable of the activity, together with duly completed **Personal History Form (PHF) and scanned copies of educational certificates.**
- 3) Please send your applications only via email to: ragelk@who.int
- 4) We regret that due to large volume of applications normally received, applications cannot be acknowledged individually.
- 5) This vacancy is open to all Sri Lankan Nationals (all genders). *Qualified female candidates are encouraged to apply*

"WHO is committed to workforce diversity". "Any attempt to unduly influence WHO's selection process will lead to automatic disqualification of the applicant."



WHO has a smoke-free environment and does not recruit smokers or other tobacco users

15 June 2020

NG/kr.


Dr Olivia Corazon Nieves
Public Health Administrator

17 JUNE 2020

