LIBERIA MEDICINES & HEALTH PRODUCTS REGULATORY AUTHORITY (LMHRA)
P. O. Box 1994 VP Road, Old Road
Oldest Congo Town
1000 Monrovia, 10 Liberia
West Africa

Terms of Reference for Pharmacovigilance Consultant

1. Background

The Liberia Medicines & Health Products Regulatory Authority (LMHRA) was established on September 10, 2010 to ensure that all medicines and health products in the national supply chain of Liberia are safe, effective and of good quality. The LMHRA plays key roles in monitoring the safety of medicines and health products through the Department of Pharmacovigilance & Clinical Trials. Therefore, the effective functioning of the PV/CT Department largely depends upon the requisite trainings and skills to carry out work operations.

Due to increased availability and use of medicines and health products for the management and control of diseases, there is the need to monitor adverse drug reactions (ADRs). In some countries, ADRs are ranked among the top leading causes of mortality despite the fact that most of them can be preventable. In addition, management of ADRs require substantial amount of resources which can be a burden on healthcare delivery system. As a result of the increase in over-the-counter medicines, self-medication is on the rise and thus posing higher risk for drug-drug interaction, over dosage and other drug related problems. There is need for vigilance at all healthcare facilities; also at border posts on medicine importation due to porous borders and availability of counterfeit and substandard medicines in the market. It is thus, essential to implement a robust Pharmacovigilance system to monitor the safety of these medicines at all times and at all levels of the healthcare system.

2. Objectives (General and Specific)

The consultancy is intended to strengthen the capacity of PV/CT staff to become efficient in monitoring the safety of all medicines and health products, and support the collection, assessment (analysis), documentation and communication of reports on ADR surveillance in Liberia.

Specifics

Specifically, the following areas will be covered by the consultancy:

- *SWOT analysis of the Pharmacovigilance system of LMHRA*
- *Review available Pharmacovigilance documents to conform to acceptable best practice*
- *Identify and draft PV development plan*
- *Identification and develop template for SOPs for all PV process*
- *Provide hand-on training on causality assessment of adverse drug reactions for PV staff*

3. Scope of Work and methodology

During the consultancy, the PV/CT Department is expected to undergo system review and strengthening. This will occur in 4 phases, but this advert is for Phase I only: Assessment of National PV System

4. *Phase 1: Assessment of National PV System*

Due to the COVID-19 Pandemic, it is expected that the first phase of the consultancy will be done through virtual meetings. The consultant will conduct SWOT (Strengths, Weaknesses, Opportunities, and Threats) analysis virtually to understand the workings of LMHRA's safety monitoring department.

Assessment of the National PV System will be undertaken using the WHO Global Benchmarking Tool (GBT) and the Indicator-Based Pharmacovigilance Assessment Tool (IPAT)[12]. A pharmacovigilance system is defined as a system used by an organization to fulfil its legal tasks and responsibilities in relation to pharmacovigilance and designed to monitor the safety of authorized medicinal products and detect any change to their risk-benefit balance[3]. We will therefore assess the structure, processes, and outcomes of the National PV System.

Training needs of the LMHRA PV staff will also be assessed and a training plan developed based on job description and responsibilities.

The assessment of National PV System will also include a thorough mapping of national and global stakeholders involved in PV activities. This mapping will enable leveraging of existing technical, infrastructural, and financial resources and foster collaboration between PV actors to avoid duplication of efforts and create more impact.

5. *Deliverables*

- *Outcome of National PV System assessment*
- *Strategy and plan to improve the National PV System including identifying PV training needs of LMHRA PV staff*

6. *Duration*

Duration of the consultancy shall be ten (10) working days (to be stipulated in the contract). The current period of consultancy will cover phase 1 only.

7. *Payment modalities*

Payment modalities shall be stipulated in the final contract.

8. *Candidate profile*

The Pharmacovigilance Consultant should have a strong subject matter understanding of PV and safety operations processes (including causality assessment, post market surveillance, etc.) capabilities,

[1] World Health Organization. WHO pharmacovigilance indicators—a practical manual for the assessment of pharmacovigilance systems. 2015. https://www.who.int/medicines/areas/quality_safety/safety_efficacy/EMP_PV_Indicators_web_ready_v2.pdf. Accessed 22 June 2020.
[2] Strengthening Pharmaceutical Systems (SPS) Program S. Indicator-based pharmacovigilance assessment tool: manual for conducting assessments in developing countries. Arlington: Management Sciences for Health; 2009.
[3] https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-good-pharmacovigilance-practices-module-i-pharmacovigilance-systems-their-quality-systems_en.pdf. Accessed 22 June 2020.

regulations and systems. The consultant should have project management skills and have proven experience in working and strengthening National PV Systems.

9. Application Process and contact details

Interested Candidates should address applications to the following address:

Director of Human Resource (HR)
Liberia Medicines & Health Products Regulatory Authority (LMHRA)
VP Road, Old Road, Oldest Congo Town
P.O. Box 1994 1000 Monrovia, 10 Liberia
Tel: +231 888-140-555; +231 778-140-555

Send only to the following emails:
Email: info@lmhra.gov.lr; jm.redd@lmhra.gov.lr

Note: Deadline for submission of all applications: September 5, 2020.