REQUEST FOR EXPRESSIONS OF INTEREST

INDIVIDUAL CONSULTANTS

REQUESTS TO HIRE INDIVIDUAL CONSULTANTS TO DEVELOP RECOMMENDATIONS FOR THE HARMONIZATION OF TOOLS, PROTOCOLS AND PRACTICES FOR THE GENERATION OF SAFETY EVIDENCE.

Date: March 10, 2025

PROCUREMENT REFERENCE NO: ACDC/SAI/CS/02

1. BACKGROUND

Africa Centers for Disease Control and Prevention (Africa CDC) is an autonomous technical institution of the African Union that supports the Member States (MS) in planning, preparing, and responding effectively and efficiently to the continent's public health threats and outbreaks. Leadership principles of credibility, ownership, delegated authority, timely dissemination of information, transparency, accountability, and value addition guide Africa CDC.

Africa faces a growing demand for robust systems to monitor the safety of medical products, including vaccines, medicines, and medical devices. The diverse regulatory landscapes across African countries and varied practices and tools for generating safety evidence pose challenges to effective pharmacovigilance and post-market surveillance.

Recognizing these challenges, Africa CDC seeks to harmonize tools, protocols, and practices for generating safety evidence. This effort will involve synthesizing existing frameworks, guidelines, and best practices to create a unified vaccine safety assessment and surveillance approach. Key strategies, such as standardized protocols, cross-border collaboration, transparent data sharing, risk assessment frameworks, adaptive regulatory approaches, stakeholder engagement, and capacity building, will be integrated into the recommendations to ensure holistic and effective

responses.

The consultancy outlined in this ToR will focus on developing recommendations for harmonizing safety monitoring approaches across African countries, ensuring alignment with global best practices and regional needs. Africa CDC Science Directorate is seeking 2 (two) consultants for 3 (three) months.

2. TERMS OF REFERENCE (TOR) FOR CONSULTANCY POSITION:

2.1. SCOPE OF WORK:

Working in close collaboration with Africa CDC, CEPI, SPEAC and Member States, the consultant will:

I. Review and Analysis:
- Conduct a review of existing pharmacovigilance frameworks (including vaccine safety), protocols, and practices at continental, regional, and national levels.
- Identify gaps and areas for improvement in current tools and approaches used during vaccine deployment in public health emergencies.

II. Stakeholder Engagement:
- Collaborate with key stakeholders, including regulatory authorities, immunization programs, and pharmacovigilance systems, to collect insights and recommendations.

III. Development of Recommendations:
- Develop recommendations for harmonized tools, protocols, and practices for vaccine safety evidence generation, incorporating global best practices and tailoring them to the African context.
- Integrate strategies for risk assessment, adaptive regulatory approaches, and capacity building.

IV. Mechanism Development:
- Propose mechanisms for ongoing collaboration between key pharmacovigilance stakeholders and member States to ensure sustainability.
- Establish frameworks for stakeholder engagement and coordination during vaccine deployment.

V. Documentation and Reporting:
- Compile a comprehensive report detailing the harmonized recommendations, including practical steps for implementation.
- Present findings to Africa CDC, CEPI, and other stakeholders as required.

3. DELIVERABLES:

- Situational Analysis Report: A detailed report summarizing existing tools, protocols, and practices for safety evidence generation in Africa.
- Recommendations for harmonization of tools, protocols, and practices tailored to the African context developed
- Mechanisms for ongoing collaboration and knowledge sharing between Africa CDC and partners developed
- Documentation of stakeholder engagements, including key insights and feedback.

4. QUALIFICATIONS AND EXPERIENCE OF CONSULTANT:

- Master's Degree in Pharmacovigilance and Pharmacoepidemiology, Clinical Pharmacy, Pharmacology, Public Health, or related field and 12 years of relevant experience.

OR

- PhD in Pharmacovigilance and Pharmacoepidemiology, Clinical Pharmacy, Pharmacology, Public Health, or related field and 8 years of relevant experience.

5. REQUIRED SKILLS AND COMPETENCIES

A. Functional skills

- Experience in public health programmes including providing technical assistance in strengthening pharmaceutical systems in the continent
- Experience designing, implementing, and monitoring pharmacovigilance systems
- Excellent diplomatic, representational, interpersonal and communication skills, including experience with successfully interacting with stakeholders and decision-makers in technical and other professional settings.
- Demonstrated project planning and management skills for organizing, planning and executing projects from conception through implementation.
- Excellent technical writing skills, in addition to narrative and financial reporting skills.
- Excellent computer skills, including word-processing capabilities, proficiency with e-mail and internet applications, experience in using office software applications such as MS Excel, PowerPoint and Word

B. Personal Abilities

- Strong problem-solving abilities
- Ability to plan and predict potential and emerging barriers
- Ability to build strong relationships internally and with external stakeholders
- High level of autonomy at work, yet with profound team spirit
- Ability to work under pressure, with minimal supervision, and in a culturally diverse team
- Adaptive, patient, resourceful, resilient and flexible

6. LANGUAGE REQUIREMENT:

Applicants must be proficient in at least one of the working languages of the African Union (English, French, Arabic or Portuguese). Knowledge of two or more of African Union working languages would be an added advantage.

7. OBJECTIVES OF CONSULTANCY:

The primary objectives of this initiative are to:

- Develop harmonized tools, protocols, and practices for generating safety evidence tailored to Africa's regulatory and health system contexts.
- Identify gaps in current PV frameworks and provide recommendations for their improvement.
- Strengthen regional collaboration and stakeholder engagement in pharmacovigilance and post-market surveillance.
- Enhance the capacity of African Member States to generate and utilize safety evidence in public health decision-making.

8. EXPECTED OUTCOME BY THE END OF THE EXERCISE, THE FOLLOWING OUTCOME ARE ANTICIPATED:

- A report summarizing existing tools, protocols, and practices for safety evidence generation in Africa.
- Actionable recommendations for harmonization of tools, protocols, and practices tailored to the African context.
- Frameworks for ongoing collaboration, knowledge sharing, and stakeholder coordination.
- Documentation of key insights and feedback from stakeholder engagements.

9. METHOD TO ACHIEVE THESE OBJECTIVE, THE FOLLOWING APPROACH WILL BE EMPLOYED:

A. Review and Analysis:
   - Conduct a comprehensive review of existing PV frameworks, tools, and practices at national, regional, and continental levels.
   - Identify gaps and areas for improvement in safety monitoring during public health emergencies.

B. Stakeholder Engagement
   - Collaborate with Member States, regulatory authorities, immunization programs, and PV centers to gather insights and best practices.

- Facilitate consultations and workshops to engage stakeholders in the development process.

C. Development of Harmonized Recommendations
   - Synthesize findings from reviews and stakeholder consultations to draft harmonized tools, protocols, and practices.
   - Align recommendations with global standards, such as those from WHO, ICH, and CIOMS, while tailoring them to the African context.

D. Validation and Finalization
   - Conduct validation workshops with key stakeholders to refine recommendations
   - Finalize a comprehensive report detailing harmonized tools, protocols, and practices, along with implementation guidelines.

10. DURATION OF CONSULTANCY:

The consultancy is expected to last (3) three months, with deliverables submitted progressively based on agreed timelines.

11. REPORTING AND SUPERVISION:

The consultants will report to the Africa CDC Pharmacovigilance Unit and work in close collaboration with other units within Africa CDC and relevant stakeholders.

12. DUTY STATION:

The consultants shall work from the Head Quarters of Africa CDC in Addis Ababa, Ethiopia.

13. EVALUATION AND QUALIFICATION CRITERIA:

1. General experience (10 Points)
2. Specific Experience relevant to the assignment (50 Points)
3. Qualifications (30 Points)
4. Language (10 Points)

14. CONSULTANCY FEE:

Remuneration is payable monthly. It is negotiable but based on qualifications and experience and the applicable AU rates for the level of the consultancy. Fees payable do not include costs associated with assignment related travels, coordination/organization of project related activities and events, stakeholder dialogues, consultations and workshops. These costs will be met by the Africa CDC.

15. APPLICATION SPECIFICATIONS:

Interested consultants should include in their application the following:

- Relevant experience related to the assignment
- Contacts of at least 3 organizations previously worked for
- Curriculum Vitae
- Cover letter (not more than two pages long)

The Africa CDC now invites eligible **Individual Consultants** to indicate their interest in providing the Services. Interested candidate must provide information demonstrating that he/she has the required qualifications and relevant experience to perform the Services.

The Consultants will be selected in accordance with the Individual Selection method set out in theAU Procurement Manual V.2.0. Further information can be obtained at the address below during office hours 8:00-13:00hrs and14:00-17:00 hours, Addis Ababa Time. Interested consultants must respond to the call by sending their comprehensive CVs in a written form following **the above criteria** to the emails below before 15:00 Hours Addis Ababa Time on 24 March 2025.

Africa Centres for Diseases Control and Prevention,
Attn: Director of Management and Administration.
Africa CDC Office Complex, Haile
Garment Area, Addis Ababa, Ethiopia
E-mails: **Tender@africacdc.org** **and** **Abuj@africacdc.org**