MINISTRY OF HEALTH: PHARMACY AND POISONS

Recruitment of a consultancy to support the Kenya PPB in the establishment of Bioequivalence Framework

Introduction

This procurement will be managed by Supporting Health Initiatives (SHI), a Division of Wits Health Consortium Pty Ltd (WHC) for and on behalf of the Kenya PPB with funding from the Bill & Melinda Gates Foundation.

WHC is a wholly owned company of the University of the Witwatersrand, Johannesburg, established to serve as the legal entity through which the University, and primarily the Faculty of Health Sciences, can conduct research, entrepreneurial and philanthropic funded activities, and services (including clinical services). WHC is set up on a Divisional basis of which SHI is a Division of WHC.

SHI in collaboration with WHC has developed a strong track record of delivering on assignments in Africa. SHI's operations and business teams have demonstrated the capacity to quickly align with partners, distribute funds, and oversee implementation. SHI has been intimately involved in the successful backlog clearance of National Regulatory Authorities as well as the provision of support to achieve WHO ML3.

Background information

Bioequivalence is the biochemical similarity of two dosage forms or active ingredients with similar blood concentration levels that produce the same physiological activity. Pharmacokinetic studies need to be done to determine whether commercial products and generic drugs share important therapeutic attributes. Pharmaceutical equivalence is present when two drugs release the active ingredient into the blood stream at the same amount, same rate and same quality. It is important to note that bioequivalence testing for generic drugs does not require a full clinical trial that the brand product went through. Bioequivalence involves testing a generic drug against the brand-name drug on two small groups of test subjects, drawing timed blood samples from each patient and demonstrating through statistical analysis that any differences in the bioavailability in the two groups is not clinically significant.

The Kenya Pharmacy and Poisons Board (PPB) proposes to implement a BE approach in the registration of generic drugs in Kenya. This will be important in ensuring that only quality generic drugs are registered in the country. It will also be building capacity in the regulation of biosimilars in the country occasioned by the push to localize the manufacture of various critical classes of pharmaceuticals. Hence, the Board seeks an individual consultant who will assist it in the conducting of feasibility studies and risk assessment on introduction of mandatory BE on locally produced pharmaceutical products.

Objectives of the Consultancy

The objectives of the consultancy shall be: -

1. To understand bioequivalence and its implications in the registration of pharmaceuticals globally and locally.
2. To determine the requirements for the implementation of a BE approach and consolidate Bioequivalence modules in the Country.
3. To review the Bioequivalence Framework and propose implementation procedures of BE in Kenya
4. To determine the key issues, risks, opportunities and make recommendations accordingly
5. To compile a detailed document on the best practice, advantages, cost implications, and implementation plan for bioequivalence in Kenya.
6. To present the findings in various stakeholders' forums.

Scope

The consultancy will be limited to understanding BE practice globally and locally, determining the requirements for the implementation of BE testing for the Pharmacy and Poisons Board and the compilation of a detailed BE document to be used as a reference point in Kenya. Additionally, it will involve capacity building and making presentations to various stakeholders and consolidating their input in the findings.

Expected Deliverables

1. Approved inception report detailing the scope, methodology and timelines.
2. Report on global practice of bioequivalence in regulation of generic drugs.
3. Feasibility study and risk-benefit assessment reports
4. Contextual analysis. Review of organizational reports on BE, if any.
5. Formulation of BE implementation plan. This should indicate the requirements and costing of BE for the regulator and drug companies.
6. Detailed report on BE for Kenya with an implementation matrix and roadmap.
7. From the start of the consultancy agree and schedule regular meetings with the PPB, SHI and BMGF.

Duration and Location

The consultancy will be for an initial three (3) months during which period the consultant will be expected to produce a high-quality document. Extensions may be granted without changes in the negotiated consultancy fee. The consultant can work from anywhere but must be able to travel during engagement with the Pharmacy and Poisons Board. Hybrid working is acceptable for this consultancy although the Consultant will be expected to travel to and within Kenya for stakeholder sensitization and meetings with KPPB top management. The PPB will provide for in country travel.

Requirements and Qualifications

The consultant shall possess the following qualifications:

1. A degree in pharmacy or pharmaceutical sciences.
2. A master's degree in pharmacy, strategic management or project management.
3. Extensive experience regarding bioequivalence studies and assessment of BE requirements for generic products, preferably within an NRA.
4. Five years' experience in the formulation of strategies in the healthcare sector of a developing country.
5. Excellent report writing skills.
6. Experience in the execution of projects funded by development partners will be an added advantage.

Selection Criteria

Technical Score

Qualifications and Experience: 35 points

Strategy Formulation, Writing Skills and Methodology: 35 points

Financial Score

Price offer: 30 points. Only applicants attaining 56 points in the technical score will be considered forfinancial evaluation.

Application process

Terms of Reference can be obtained from:

Supporting Health Initiatives website: www.supportinghi.co.za under the tab TENDERS.
Kenya Pharmacy Poisons Board website: www.pharmacyboardkenya.org

Submitting Your Application

Your application must contain the following information:

1. Detailed technical proposal including the methodology.
2. A separate financial proposal. Financial proposals should be submitted in US Dollars and include a payment schedule against agreed deliverables and timeframes.
3. Samples of three recent works including the email addresses and phone numbers of the clients.

Submissions must be submitted no later than midnight SAST 31 January 2024.

Submissions must be sent by email to: SHIproposals@witshealth.co.za.

Non-compliance with any of the requirements listed above will result in disqualification.