Gates Foundation

REPUBLIC OF KENYA

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

EXPRESSION OF INTEREST FOR DEVELOPMENT OF SOFTWARE AS A MEDICAL DEVICE (SaMD) GUIDELINE FOR USE BY THE PHARMACY AND POISONS BOARD

1. Purpose

The Pharmacy and Poisons Board (PPB) is the National Regulatory Authority mandated to protect the health of the public by regulating the profession of pharmacy and ensuring quality, safety and efficacy of medical products and health technologies in Kenya. In view of its regulatory functions, the PPB seeks to enhance its regulatory status by attaining the WHO categorization of Maturity Level 3 (hereinafter referred to as "ML.3") in line with the WHO Global Benchmarking Tool (GBT). PPB Conducted the Piloting of the GBT Tool +Medical Devices (MD) in 2022 during the WHO-Benchmarking exercise conducted from June/July 2022. From this exercise regulatory oversight of Software as a Medical Device (SaMD) was identified as a gap.

The development and implementation of this guidance document will support the regulatory oversight of Software as a Medical Device (SaMD) by the PPB.

2. Scope

This guidance document will seek to provide definition and classification of SaMD. Additionally, the Criteria for determining when a software should be considered as a medical device.

The policy development and guideline implementation for software as a medical device is primarily the mandate of PPB. There is already recognition of this sub-set of medical devices stipulated in pre-existing local guideline under the section: "Appropriate documentation is required if the medical devices are either stand-alone software or rely upon software". However, PPB lacks a fully-fledged process and platform for reviewing (and making determinations) pre-market technical submissions and proposed post-market activities.

3. Objective

The objectives of this guidance document are outlined as below;

i. To establish a comprehensive and standardized process for reviewing pre-market technical submissions for SaMD
ii. Outline a structured framework for determining proposed post-market activities for SaMD
iii. To enhance the safety and efficacy of SaMD through effective regulatory oversight.

4. Roles and Responsibilities of the Consultancy Firm/Consultant

The consultant aims to:

i. Review and analyze guidelines for Software as a Medical Device (SaMD) from IMDRF, US FDA, HAS-Singapore, and WHO.
ii. Develop the guidance document for regulatory oversight of SaMD.
iii. Develop use-case testing components for regulatory compliance, software verification and validation, and risk management and safety testing.
iv. To conduct stakeholder engagements and collect inputs for consideration from stakeholders including industry players
v. Conduct a workshop(s) to sensitize stakeholders on the developed guidelines for SaMD.

5. Responsibilities & deliverables

5.1 Responsibilities

The consultant will employ a multi-faceted approach to achieve the outlined objectives:

i. Collaborative Outcomes Reporting: This methodology will foster engagement with key experts from the Pharmacy and Poisons Board, the Ministry of Health, industry stakeholders, and other relevant parties to ensure alignment with the consultancy's objectives.
ii. Literature Review and Analysis: A thorough review of current guidelines and best practices will be conducted to identify gaps and opportunities for improvement in the regulatory framework for medical devices in Kenya.
iii. Workshops and Stakeholder Engagement: Facilitate workshops to gather insights and promote collaboration among stakeholders to ensure buy-in and effective implementation of the guidelines.

To facilitate and support the consultant;

i. The Staff of PPB as the secretariat for this project, will providing support and guidance on the expected outcomes and coordination of activities.

ii. Through the PPB, the consultant will engage experts at the Ministry of Health, Industry players and other key stakeholders to perform tasks in alignment to the above three key objectives.

5.2 Deliverables

The consultant will produce the following deliverables:

i. An inception report outlining the methodology and approach for the consultancy.
ii. A comprehensive report analyzing the reviewed guidelines for SaMD from IMDRF, US FDA, HSA, and WHO, highlighting key findings for adoption by Kenya.
iii. A report providing an analysis of guidelines from IMDRF, WHO, US FDA, and HAS-Singapore on SaMD, with actionable recommendations for regulatory use.
iv. A developed use-case testing component report for compliance, verification, and risk management.
v. A report summarizing key recommendations from stakeholder sensitization workshops regarding the developed SaMD guidelines.
vi. A final report integrating all findings and recommendations.
vii. Guideline for regulatory oversight of SaMD for use by the Pharmacy and Poisons Board

6. Timelines & performance tracking

The consultancy is expected to be completed within (3) Months or 90 calendar days. To track the performance during the course of the project, reports as outline above will be submitted to the PPB as secretariat for this project.

The final draft guideline for regulatory oversight for SaMD will be reviewed for acceptance by the PPB management.

7. Payment Term

Payment will be made based on the following:

i. A timesheet is provided with each invoice, divided into three parts with a first payment of 25% upon awarding of the consultancy; 25 upon submission of Draft guideline with accompanying report and a final 50 % upon satisfactory completion of the final draft guideline, use case testing component report, final report integrating all findings and sensitization workshop to the Staff of PPB.
ii. Each invoice and timesheet submitted is to be approved by PPB before release of the payment.
iii. Each invoice fully complies with development partner (the Gates Foundation) policies and procedures

8. Powers of the Consultancy Firm

The Consultant serves in an advisory capacity and does not have decision-making authority. They are mandated to provide the PPB with expert technical advice/recommendations to inform and enhance decision-making processes.

9. Composition of the Consultancy Firm

The Consultancy firm shall be required to meet the following key criteria:

i. Are people of high integrity;
ii. Have wide experience in the review highly technical scientific document around the regulation of Medical devices and Software as a Medical Device in particular and;
iii. Possess excellent analytical and writing skills.
iv. The consultancy firm is appointed for a period of three (3) months.
v. The work for the consultant shall be coordinated by the Deputy Director, Product Evaluation and Registration or his/her designee, the Head of Medical Devices and In-Vitro Diagnostics and a secretary designated from the PPB's Product Evaluation and Registration Department.

10. Venue of Meetings

The Consultant and experts can hold meetings at either PPB offices or at the venue of their convenience.

11. Rules of Conduct

i. The Consultant is required to adhere to the provisions of the Manual for Technical & Expert Advisory Committees, 2022 (CEO/CSL/MAN/008) to govern their conduct.
ii. Guiding Principles: The consultant shall adhere to the Principles of Good Regulatory Practices (GRP) and the Principles of Public Service in their conduct
iii. Declaration of Interest:
    a. The consultant must avoid conflicts of interest between their private activities and their part in the conduct of the Board's business.
    b. At the inaugural meeting, consultant shall sign the Declaration of Interest Form (FOM 021/QMS/SOP/003) which contains the instructions for declaration of interest and specifies the conflict-of-interest handling mechanisms.
    c. Before every meeting, each member is required to declare any interest based on the agenda of the meeting by signing the Declaration of Interest Form – Abridged Version (FOM/053/QMS/SOP/003).

iv. Commitment to Confidentiality:

a. The consultant is required to uphold confidentiality in the course of duty.
b. At the inaugural meeting, Consultant shall signify this commitment by signing the Commitment to Confidentiality Form (FOM 022/QMS/SOP/003)

12. Indemnification and Legal Assistance

The Consultancy firm serve on contract basis and are not liable to legal suits.

13. Reporting

Shall report their recommendations/advice to the PPB through Head of Medical Devices and In-Vitro Diagnostics.

14. Review and assessment of the performance of the Consultancy firm

The evaluation of performance of the consultancy firm is done by the Chief Executive Officer Pharmacy and Poisons Board.

15. Effective Date & Review

This Terms of Reference is effective from 18th February 2025 and shall be reviewed periodically.

16. Supporting Partner/s

This project is funded by the Gates foundation, as development partners.

Signed: .....

Dr. F.M. Siyoi
CHIEF EXECUTIVE OFFICER