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REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

GUIDANCE FOR OUTSOURCING LABORATORY TESTING SERVICES

APRIL 2023

Citation and address

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Abbreviations and Acronyms

The following abbreviations and acronyms are used in this guidance document:

CEO:	Chief Executive Officer
EDQM:	European Directorate for the Quality of Medicines and Healthcare
HPTs:	Health Product and Technologies
IEC:	International Electrotechnical Commission
ISO:	International Organization for Standardization
LTR	Local technical representative
MAH	Market authorization holder
OOS:	Out of Specification
PPB:	Pharmacy and Poisons Board
QC:	Quality Control
QCL:	Quality Control Laboratory
QMS:	Quality Management Systems

FOREWORD

The Pharmacy and Poisons Board is committed to a policy of providing exemplary service with respect to performing accurate testing and analysis of Health Products and technologies. In this regard, the Board may outsource testing services as part of its mandate of prescribing a system of sampling, analysis and other testing procedures of finished health products released into the market to ensure compliance with the labeled specifications. This document is intended as a general guidance for the Board when externally provided products and services affecting laboratory activities are used, with a special focus on testing services.

The Board shall ensure that only suitable externally provided products and services that affect laboratory activities are used, when such products and services are intended for incorporation into the laboratory's own activities and are used to support the operation of the laboratory.

This guidance document seeks to inform persons on the manner of undertaking subcontracting agreements by the Board as a body corporate capable of entering into agreements. The policies and relevant laws relating to contracting by government agencies shall apply as necessary, to the subcontracting of a laboratory under these guidelines.

Thank you.

DR. F.M SIYOI

Chief Executive Officer, Pharmacy and Poisons Board

GLOSSARY OF TERMS

Board	The term here refers to the Pharmacy and Poisons Board
Contract	a legally binding document that outlines the terms and conditions governing the provision of goods and services.
Contract giver	refers to an individual, organization, or entity that is responsible for providing a contract or agreement to provide products or services to another party, usually referred to as the " contract acceptor."
Contract acceptor	refers to a party who agrees to the terms and conditions outlined in a contract. The acceptor may be an individual, organization, or entity that gives their consent to the contract, indicating their willingness to be bound by the terms of the agreement.
Qualification:	Action of proving that the external service provider systems work correctly and actually lead to the expected results.
Analytical test report	An analytical test report usually includes a description of the test procedure(s) employed, results of the analysis, discussion and conclusions and/or recommendations for one or more samples submitted for testing
Certificate Of Analysis	The list of test procedures applied to a particular sample with the results obtained and the acceptance criteria applied. It indicates whether or not the sample complies with the specification
Management review	A formal, documented review of the key performance indicators of a quality management system performed by top management.
Out-of-Specification (OOS) result	All test results that fall outside the specifications or acceptance criteria established in product dossiers, drug master files, pharmacopoeias or by the manufacturer

Outsourcing/ Sub-contracting services	refers to the practice of contracting or delegating specific business processes, tasks, or functions to external third-party service providers or organizations. These external service providers, often referred to as outsourcing vendors or partners, assume responsibility for performing the designated tasks on behalf of the outsourcing client or company.

1. Introduction

1.1 General information

1.1.1 Under the Laws of Kenya (Cap 244) the Pharmacy and Poisons Board is legally mandated to prescribe a system for sampling, analysis, and other testing procedures of finished health products released into the market to ensure compliance with the labeled specifications.

1.1.2 This guidance seeks to inform external laboratories on the manner of undertaking subcontracting agreements by the Board and guide on the alternative systems for sampling, analysis, and other testing procedures of finished products in the furtherance of section 3B (2)(K) of the Pharmacy and Poisons Act CAP 244. The guidance may also find use by clients intending to appeal test results and/or regulatory actions arising from the test results.

1.1.3 The Policies and relevant laws relating to contracting by Government agencies shall apply, as necessary, to the subcontracting of a laboratory under these guidelines.

1.1.4 The Board shall assume responsibility for the results of the selected external service providers with its customers.

1.2 Reasons for outsourcing test services

1.2.1 The Board may outsource testing services for the following reasons:

- Special techniques/equipment not available at the Board.
- Confirmatory testing by a second laboratory
- Work-sharing (e.g., in cases of pandemics)
- Excessive workload
- Lack of qualifications, competency, or resources

1.3 Selection of External providers

1.3.1 The Board shall apply the following selection criteria during the selection phase:

- WHO prequalified Laboratories;
- ISO 17025 accredited laboratories;
- Other relevant recognized institutions with relevant recognized accreditations/certifications for the tests of interest such as ISO 13485 for medical devices.

1.3.2 The Board shall be responsible for assessing the suitability and competence of the external service provider to successfully carry out the work or tests required, for approval for contract activities and to ensure compliance with ISO 17025 requirements and any other prescribed requirements by the Board.

1.3.3 For external service providers that meet the set criteria in 1.3.1, The Board shall request a copy of the latest WHO or ISO inspection report and if satisfied with the compliance status from the report, the Board shall prepare a qualification report in the prescribed format and select the laboratory as an outsourced test service provider.

1.3.4 For external service providers that do not meet the criteria in 1.3.1 but have been identified to have the capacity to carry out tests not identified in any of WHO prequalified or ISO-accredited laboratories, the Board shall carry out full assessment of the facility in accordance with WHO and ISO 17025 standards, prepare an inspection report, and if satisfied with the compliance status of the facility, the Board shall prepare a qualification report in the prescribed format and select the laboratory as an outsourced test service provider.

1.3.5 The Board shall, in consultation with the selected service provider enter into a written contract that clearly establishes the

responsibilities of each party, covering the outsourced activities, the products or operations to which they are related, communication processes relating to the outsourced activities, and any technical and legal arrangements made in connection with it.

1.4 Responsibilities of the Parties during Outsourcing

The Board (Contract giver) shall:

1.4.1 Provide all the relevant information related to the outsourced testing, including health and safety, and the destination of the samples after testing archiving of the results (records).

1.4.2 Provide the required quantity of the sample to be tested along with other relevant information including approved methods of analysis.

1.4.3 Under exceptional circumstances, obtain and supply reference standards from the manufacturer.

1.4.4 Review the results and the performance of the testing provider.

1.4.5 Undertake regulatory action based on a defined decision tree.

1.4.6 define the procedure for investigating out-of-specification (OOS) results

1.4.7 define the ownership of information and any consequent actions.

1.5 The external service provider (contract acceptor) shall:

1.5.1 be independent, assure confidentiality, and have no conflicts of interest

1.5.2 assure the conditions that exist to perform the test (premises, equipment, infrastructure, knowledge, experience, competence of the personnel, documentation, quality system).

1.5.3 not outsource any of the provided work to a third party.

1.5.4 inform the Board about any deviations or changes to methods/protocols.

1.5.5 maintain the records related to the outsourced activity.

1.5.6 allow the Board to carry out an audit, when necessary.

1.6 Requirements of the contract

1.6.1 The contract drawn between the Board and the selected laboratory for subcontracting shall include the following as a minimum;

1.6.2 The testing scope and requirements for reporting.

1.6.3 Confidentiality clause

1.6.4 Financing arrangements

1.6.5 Period of the agreement and termination conditions

1.6.6 Dispute settlement and jurisdiction

1.6.7 Signatory section

1.7 Communication

1.7.1 Communication of test results to the client (MAH/LTR) or the public shall be undertaken by the contract giver. It shall be improper for the contract acceptor to communicate results.

1.7.2 Any requests for additional samples or reference materials shall be communicated through the contract giver.

1.7.3 The contract giver may communicate to the mutually agreed laboratory subcontracted by the contract acceptor.

1.8 Reporting of the results from testing service provider

1.8.1 The Board shall engage the service provider in accordance with internal procedures for coordinating testing services with subcontracted laboratories

1.8.2 The Board shall review the results reported by the testing service provider and prepare a laboratory report that clearly indicates the test was performed by an external service provider.

1.9 Appeal of test results

1.9.1 Clients may only appeal against test results through the Pharmacy and Poisons Board in line with the "guidelines for lodging complaints and appeals" published by the Pharmacy and Poisons Board.

1.9.2 Any appeals received by contracted laboratories shall promptly be communicated to the contract giver.

1.10 Performance monitoring and evaluation of the external providers

1.10.1 The Board shall apply the following criteria for evaluation and monitoring the performance of a selected external service provider for requalification purposes:

- Quality of products or services
- Timeliness /testing turnaround time
- Conformity of supply in relation to orders
- Customer friendliness
- Price policy
- Goodwill

References

1. European Directorate for the Quality of Medicines Guidelines on Externally provided products and services PA/PH/OMCL(20)77R2 https://www.edqm.eu/documents/52006/128968/externally-provided-products-and-services.pdf/214bc692-d068-cead-f898-4d8e14d16baf?t=1628491793484
2. International Organization for Standardization. General requirements for the competence of testing and calibration laboratories. ISO/IEC 17025:2017.
3. International Organization for Standardization. Quality management systems requirements. ISO/IEC 9001:2015.
4. WHO Good practices for pharmaceutical quality control laboratories TRS No. 957, 2010 Annex 1
5. WHO good manufacturing practices for pharmaceutical products: main principles TRS No. 986, Annex 2

Annex 1: Process flow chart