MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

REPORT ON RISK- BASED POST MARKETING SURVEILLANCE OF THE QUALITY OF SELECTED MEDICINES IN KENYA

A joint activity with United States Pharmacopeial Convention-Promoting the Quality of Medicines Plus (USP-PQM+) programme

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1. The President's Malaria Initiative (PMI)
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    - Division of Reproductive and Maternal Health (MOH)
    - Division of National Malaria Program (MOH)
    - National Leprosy and Tuberculosis Program (MOH)
    - National Vaccines and Immunization Program (MOH)

Acronyms and Abbreviation

API	Active Pharmaceutical Ingredient
BP	British Pharmacopoeia
CFU	Colony Forming Units
CoA	Certificate of Analysis
GMP	Good Manufacturing Practice
IGAD	Intergovernmental Authority on Development
Int.P	International Pharmacopoeia
KEMSA	Kenya Medical Supplies Authority
LMICs	Low and middle- income countries
MEDS	Mission for Essential Drugs and Supplies
MedRS	Medicine Risk Surveillance
MNCH	Maternity, Neonatal and Child Health
MRA	Medicine Regulatory Authority
MRH	Medicine Regulatory Harmonization
NQCL	National Quality Control Laboratory
PMI	President's Malaria Initiative
PMS	Post-Marketing Surveillance
PPB	Pharmacy and Poisons Board
PQM+	Promoting the Quality of Medicines Plus
PV	Pharmacovigilance
PY	Programme Year
QA	Quality Assurance
QC	Quality Control
RB PMS	Risk Based Post marketing surveillance
RMNCH	Reproductive, Maternal, New-born and Child Health
SF	Substandard/Falsified
STI	Sexually Transmitted Infections
TAMC	Total Aerobic Microbial Count
TYMC	Total Combined Yeasts/Moulds Count
UHC	Universal Health Coverage
USAID	United States Agency for International

	Development
USP	U.S. Pharmacopeial Convention
WHO	World Health Organization

1 EXECUTIVE SUMMARY

One of the key components of ensuring that the public gets quality medicine is by enforcing a comprehensive Post-Marketing Surveillance (PMS) system that involves monitoring the safety and quality of medical products and health technologies after being released to the market. Until recently PMS activities in Kenya were conducted using conventional approaches that were costly and less efficient. There was a need to incorporate a risk-based approach resulting in a scientific, convenient, efficient, and cost-effective PMS exercise.

This study aimed at carrying out a risk-based quality survey of key medicines used to manage malaria, neonatal sepsis, and postpartum hemorrhage, which are major causes of mortality in Kenya.

Historical data from the Kenya Pharmacy & Poisons Board (PPB) database were used to identify 19 (out of 47) counties in Kenya as relatively risky regions about poor-quality medicines. A stratified random sampling technique was used to identify the sampling outlets from the selected counties using the Promoting the Quality of Medicines Plus (PQM+) medicines risk assessment tool (MRS). Using this tool, the estimated sample sizes of the individual products were calculated as follows: Oxytocin 10 IU/5 IU /mL injection (100), Gentamicin 20mg/2mL injection (100), Artesunate 30 mg/60mg injection (100), and Artemether/Lumefantrine (AL) 20mg/120mg in packs of 6s tablets (70). Samples were collected from various pharmaceutical handling outlets by the PMS technical working group members and analyzed.

All the sampled products met the set quality specifications. However, the AL tablets assay showed a statistically significant wide range of values (91.1-109.7%) among various brands with brands from 3 firms being consistently near the lower limit. In addition, one brand of artemether-lumefantrine did not indicate the complete address of the manufacturing site as required by PPB guidelines. The package of one brand of oxytocin showed a storage condition of 8 - 25 °C instead of the prescribed storage conditions of 2-8 °C.

The study concludes that the quality of Artesunate, oxytocin, and gentamicin injections, as well as Artemether Lumefantrine (AL) tablets in the Kenyan market, were of acceptable quality with AL tablets requiring closer monitoring in subsequent PMS

2 Introduction

The constitution of Kenya 2010 provides that every person has the right to the highest attainable standard of health. The highest standards of health are only attainable if the quality of medical products and health technologies in the market are of the right quality.

The Pharmacy and Poisons Act CAP 244 laws of Kenya mandate the Board to regulate the trade in medical products and health technologies. Sections 3 (A)(f), 3B (2) (k, l, and m) mandate the Board to implement market surveillance ac activities to monitor the quality, safety, and efficacy of medical products and health technologies circulating in Kenya.

Medical products and health technologies are essential components of healthcare service delivery (Bigdeli, M., Jacobs, B., Tomson, G., Laing, R., Ghaffar, A., Dujardin, B., & Van Damme, W.). Sustainable Development Goal 3.8 specifically mentions the importance of "access to safe, effective, quality and affordable essential medicines and vaccines for all" as a central component of Universal Health Coverage (UHC) and Sustainable Development Goal 3 .b emphasizes the need to develop medicines to address persistent treatment gaps (Sachs). Access to good quality health products and technologies increases public confidence in healthcare systems (Kruk, M. E., Gage, A. D., Arsenault, C., Jordan, K., Leslie, H. H., Roder-DeWan, S., ... & Pate, M.).

The quality of medical products and health technologies is an important factor in disease prevention and treatment. Quality is fundamental to their effectiveness and safety, hence a healthy outcome for the patient. Ensuring quality requires the concerted effort of all stakeholders in the entire lifecycle of health products and technologies (Porter, M. E., & Teisberg, E. O.).

A very important component of ensuring that the public gets quality medicines is by establishing and implementing a Post-market surveillance (PMS) system that involves monitoring the safety and quality of a pharmaceutical drug or medical device after it has been released on the market. PMS enables the detection of Substandard and Falsified (SF) products, registration status, and the effects of storage conditions on the quality and stability of the products (Newton, P. N., Lee, S. J., Goodman, C., Fernández, F. M., Yeung, S., Phanouvong, S., ... & White, N. J.; Kramer, D. B., Baker, M., Ransford, B., Molina-Markham, A., Stewart, Q., Fu, K., & Reynolds, M. R.). Previously the PMS activities were conducted using conventional approaches and there was a need to develop a tool that would have a risk-based approach resulting in a scientific, convenient, efficient, and cost-effective PMS exercise. Given this the Med-RS tool was developed in conjunction with USP - QPM supported by USAID.

Collaboration of institutions making up the post-marketing surveillance/ pharmacovigilance Technical Working Group (PMS/PV TWG) represents a promising strategy toward the Sustainable Development Goal of ensuring access to quality, safe, and efficacious health products, and technologies. The PMS/PV TWG is comprised of the Pharmacy and Poisons Board (PPB) which is the National Medicine Regulatory Authority, Procurement agents including Kenya Medical Supplies Authority (KEMSA) and Mission for Essential Medical Supplies, Public Health Programs including the Division of Malaria Control, National AIDS and STI Control Program, National Tuberculosis Leprosy and Lung Disease Program, Maternal and Child Health Program, teaching and research institutions including Kenya Medical Research Institute and University of Nairobi and the official medicines control laboratory, National Quality Control Laboratory (NQCL).

Post-marketing surveillance is an important regulatory function in monitoring the quality of health products and technologies post-authorization.

Post-marketing surveillance (PMS) is an important regulatory function in monitoring the quality of health products and technologies that are available to the Kenyan public. The PPB in collaboration with DNMP, and NQCL set out to survey to assess the quality of anti-malarial and RMNCH medicines circulating in the Kenyan market. The Pharmacovigilance and Post Marketing Surveillance Technical Working Group (PV/PMS TWG) of the Pharmacy and Poisons Board (PPB) was established in 2020 with the support of Promoting Quality of Medicines Plus (PQM+); a United States Agency for International Development (USAID) program being implemented by United States Pharmacopoeia (USP). One of the mandates of the TWG is the development and implementation of a PMS strategy. Members of the TWG include the Pharmacy and Poisons Board, Kenya Medical Supplies Authority (KEMSA), Mission for Essential Medical Supplies (MEDS), the Public Health Programs and teaching and research institutions, and the National Quality Control Laboratory.

The selection of the drugs for sampling was done using the Medicines Risk-based Surveillance (MedRS) tool. The tool has both online and excel based versions. The PV/PMS TWG team used the excel-based version. The MRS tool uses a risk-based approach to identify the samples and the facilities from which they were sampled.

2.1 Problem statement

Malaria, neonatal sepsis, and postpartum haemorrhage are some of the leading causes of mortality in Kenya, with malaria contributing about 4% of all the reported deaths in the country (World Health Organization, Kenya: WHO statistical profile). Kenya's under-five mortality rate due to various causes was 52 deaths per 1000 live births while the neonatal mortality rate

was 22 deaths per 1000 live births (Kenya Demographic and Health Survey). The same survey reported 362 maternal deaths per 100,000 live births of which approximately 25% result from postpartum/obstetric haemorrhage. It is also estimated that about 16% of neonatal deaths in Kenya result from neonatal sepsis or tetanus (Masaba Brian Barasa)

According to the World Health Organization (WHO), it is estimated that 10% of medical products circulating in low- and middle-income countries (LMICs) are either substandard or falsified. Since 2013, WHO has received 1500 reports of cases of substandard or falsified products. Of these, antimalarials and antibiotics are the most reported. Most of the reports (42%) come from the WHO African Region, 21% from the WHO Region of the Americas, and 21% from the WHO European Region (1, 2). In Kenya, the prevalence of poor-quality medicines in the market was recorded as 4% in 2015 (3). Surveys on the quality of antimalarials, carried out between 2010-2016 in Kenya, showed that 3.6% of these medicines were of poor quality (4). A quality survey for oxytocin injection that was carried out in the IGAD region in 2019 showed that 20.9% of tested products did not meet quality specifications. In Kenya, 13.6% of the samples of oxytocin collected did not comply with the specifications (PMS report IGAD). To date, no surveys have been conducted to determine the quality of gentamicin sulphate injections circulating in the Kenyan market.

The above-mentioned challenges of the relatively high mortality rates due to malaria, neonatal sepsis, and postpartum hemorrhage, and the presence of some poor-quality medicines for the treatment of these diseases in Kenya, supported the need to carry out this PMS survey to provide the necessary data to facilitate appropriate mitigations by PPB and other relevant stakeholders.

2.2 Justification of the PMS

Quality of medicines is critical in disease prevention and treatment and calls for the concerted effort of all stakeholders who are involved in the production, procurement, regulations, prescribing, dispensing, and use of these medicines (Porter, M. E., & Teisberg, E. O.). Institution of effective Post-Marketing Surveillance (PMS) is one of the key elements that support the availability of quality medicine in a country. It enables the detection of Substandard and Falsified (SF) products, registration status, and the effects of storage conditions on the quality and stability of the products (Newton, P. N., Lee, S. J., Goodman, C., Fernández, F. M., Yeung, S., Phanouvong, S., ... & White, N. J.; Kramer, D. B., Baker, M., Ransford, B., Molina-Markham, A., Stewart, Q., Fu, K., & Reynolds, M. R.). Recently, the Kenya PV/PMS TWG which is hosted by PPB adopted the Med-RS tool which was developed by the USP - QPM program that was supported by USAID in its risk-based PV/PMS program. This program focuses on the key medicines that are used

to treat malaria, neonatal sepsis, and postpartum haemorrhage in Kenya namely: oxytocin (10 IU/5 IU /mL) injection, Gentamicin sulphate (20mg/2mL), artesunate (30 mg/ 60 mg) injection and artemether/lumefantrine (20mg/120mg in packs of 6s) tablets.

The under-five mortality rate of 52 deaths per 1000 live births and neonatal mortality rate of 22 deaths per 1000 live births were reported in the Kenya Demographic and Health Survey of 2014. The same survey reported 362 maternal deaths per 100,000 live births of which approximately 25% result from postpartum/obstetric haemorrhage. It is estimated that approximately 16% of neonatal deaths in Kenya result from neonatal sepsis or tetanus (2018, Masaba et al). The high rates of Maternal and Neonatal morbidity and mortality are associated with a combination of factors. These include delays in seeking healthcare among the population, long distances to healthcare facilities which results in inaccessibility, limited access to safe and quality medicines, and delays in the provision of care at the health facilities.

Malaria is a global health problem and WHO reported that in 2017 there were 219 million cases and 435 million deaths compared with 239 million cases in 2010 (95% CI 219 to 285 million) while in 2016, the cases were 217 million (95% CI 200 to 259 million) (World malaria report 2018). Malaria remains one of the main childhood killers in the country and therefore the quality of these life-saving commodities is of great importance. Kenya Malaria Indicator Survey, 2020 reported that Malaria remains a major public health problem in Kenya and accounts for an estimated 13% to 15% of outpatient consultations. Malaria transmission and infection risk in Kenya are mainly determined by altitude, rainfall patterns, and temperature, leading to considerable variation in malaria prevalence by season and across geographic zones. Approximately 70% of the population is at risk for malaria, including 13 million people in endemic areas and another 19 million in highland epidemic-prone and seasonal transmission areas.

Oxytocin injection is the first line of therapy for both prevention and treatment of Postpartum Haemorrhage and is formulated as a solution for injection in an ampoule. The storage requirements of Oxytocin injection are 2°C to 8°C which requires a cold chain to maintain the quality of the medicine. In resource-limited settings, the infrastructure to maintain consistent cold chain supply and storage is often lacking or weak, presenting challenges in ensuring the quality of oxytocin for the end users. Gentamicin sulphate 20mg/mL is indicated for the treatment of neonatal sepsis and formulated as a solution for injection in an ampoule.

Artemisinin-based combination therapies are the recommended first-line treatment for malaria in Kenya and are currently available as a co-formulated regular or dispersible tablet containing 20 mg of Artemether and 120 mg of Lumefantrine. In Kenya, a three-day regimen of six tablets (AL 6s) is used for the treatment of malaria in children. Artesunate injection is

recommended for the treatment of severe malaria in adult and paediatric patients (National guidelines for the diagnosis prevention and treatment of malaria in Kenya, 2010).

2.3 Prevalence of Substandard and Falsified products

Substandard products are also referred to as "out of specification" products. These are authorized medical products that fail to meet either their quality standards or specifications or both. Falsified medical products are those that deliberately or fraudulently misrepresent their identity, composition, or source. Unregistered medical products are those that have not undergone evaluation and approval by the National Medicines Regulatory Authority for the market in which they are marketed or used.

According to the World Health Organization (WHO), it is estimated that 1 in 10 medical products circulating in low- and middle-income countries (LMICs) are either substandard or falsified. Since 2013, WHO has received 1500 reports of cases of substandard or falsified products. Of these, antimalarials and antibiotics are the most reported. Most of the reports (42%) come from the WHO African Region, 21% from the WHO Region of the Americas, and 21% from the WHO European Region (1).

The prevalence of substandard and falsified medicines is known to vary between different countries and regions; the prevalence of poor-quality medicines was much higher in West Africa than in East Africa (2).

Kenya has demonstrated a decline in the prevalence of poor-quality medicines over the period 1997-2015 (3). The study shows a trend of decreasing the poor quality of medicines in the market from an average of 25% in 1997 to 4% in 2015. According to surveys on the quality of antimalarials carried out between 2010-2016 in Kenya, there has been an increasing trend in the quality of medicines circulating in the market from 84% in 2010 to 96.4% in 2016 (4). Consistent post-marketing surveillance activities, therefore, are crucial in enhancing the quality of products in the market. A quality survey for Oxytocin injection that was carried out in the IGAD region in 2019 showed that 20.9% of the samples tested did not meet quality specifications. In Kenya, 13.6 % of the samples collected did not comply with the specifications. (PMS report IGAD). To date, no surveys have been conducted to determine the quality of Gentamicin sulfate injections circulating in the Kenyan market.

This quality survey was conducted with financial support from USAID/PMI and technical support from USP/PQM+.

3 Methodology

3.1 The objective of the Survey

3.1.1 General Objective

To assess the quality of Oxytocin, Gentamicin, Artesunate, and Artemether/Lumefantrine in the Kenyan market using a risk-based approach

3.1.2 Specific Objectives

a. To determine the prevalence of sub-standard and falsified Oxytocin 10 IU/5 IU /mL injection, Gentamicin Sulphate 20mg/2mL, Artesunate 30 mg/ 60 mg Injection, and Artemether 20mg+Lumefantrine 120 mg (6s) tablets available at selected distribution levels in Kenya.
b. To determine the registration status of the medicines sampled
c. To disseminate the findings of this survey

3.2 Survey Scope and Duration

The survey covered identified facilities in selected counties (regions) as determined by the country's technical working group on PV/PMS. Based on this, the samples were collected from public, private, faith-based organizations, and non-governmental health care facilities that stocked the medicines of interest. These included importers, central procurement agencies, wholesalers, distribution hubs, hospitals, health centres, retail outlets (pharmacy and drug store), illegal outlets, and online retailers where applicable.

The survey was conducted between September and December 2021.

3.3 Selection of medicine

The medicines that were sampled and surveyed are Summarized in the table below:

Table 1 List of medicines covered in the RB-P

The medicine selection for the quality survey was based on the survey objective, and potential public health impact using a series of risk factors. These risk factors were scored using the Medicine risk assessment tool (MedRS) developed by USP/PQM+.

The risk factors that were quantified using the MedRS tool included: physical-chemical stability of medicines, GMP compliance (of manufacturers if known), distribution complexity in the medicine supply chain; patient vulnerability; extent of population exposure, and patient vulnerability. The extent of harm due to possible poor medicine quality was also considered. Additional consideration was made based on the history of the product

compliance status from previous quality surveys or poor-quality reports and market complaints.

3.4 Selection of Survey sites

Using the MRS tool, the PV/PMS TWG identified 19 of the 47 counties as relatively risky sites regarding poor-quality medicines. The survey sites were selected in consultation with the TWG-PMS experts with knowledge of the country and with technical support from USP/ PQM+ based on risk evaluation and availability of resources.

For this survey, 19 counties were selected based on the following criteria:

Epidemiological and social-economic data; major transport corridor for goods and people/ port of entry by land., prevailing climatic conditions; ease of accessibility of the site of sampling (transport and communication network); proximity to land and sea borders; the potential presence of unauthorized pharmaceutical outlets (could include smuggled/illegally imported products based on previous regulatory actions)

The proposed priority counties (regions) based on the risk criteria for sample collection per type of medicine were as indicated in Table 2

Table 2 Selected counties for sample collection

For Antimalarials	For Oxytocin	For Gentamicin
West Pokot	Busia	West Pokot
Mombasa	Mombasa	Mombasa
Migori	Nairobi	Nairobi
Vihiga	Vihiga	Kirinyaga
Kisumu	Kisumu	Kisumu
Kakamega	Samburu	Samburu
Mandera	Mandera	Garissa
Isiolo	Isiolo	Kiambu
Uasin Gishu	Uasin Gishu	Uasin Gishu
Homabay	Elgeyo Marakwet	Bungoma
Busia	Turkana	Busia
Bungoma		Turkana

The RB PMS samples were collected from across the country in different geographical areas as shown in the map below.

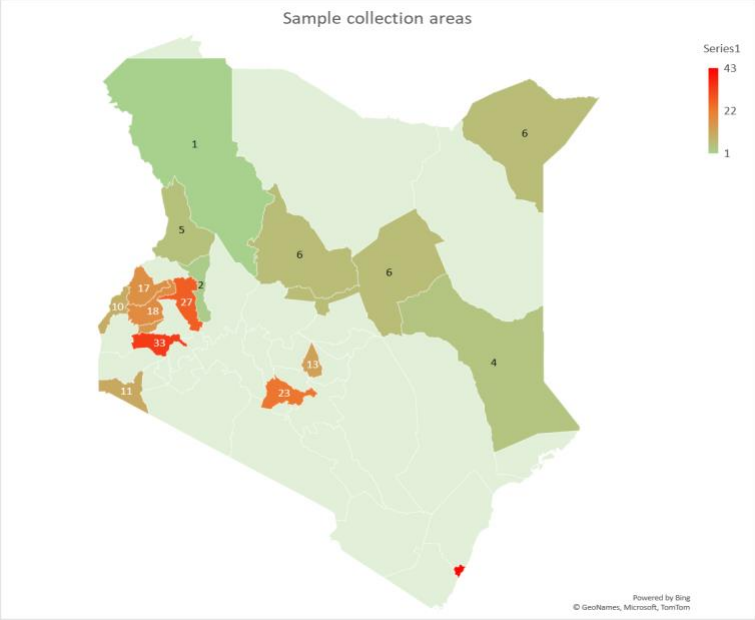

Figure 1 Distribution of selected counties for sample collection

Sample collection was done at the different levels within the drug distribution chain.

Level 1: Points of entry to the market: This included: Warehouse of importers/ manufacturers, and central and regional medical stores. NGO central stores, Procurement centres, or other facilities supplied directly within various programs, central wholesalers, and/or distributors.

Level II: Regulated wholesalers and distributors: Pharmacies.

Level III: Regulated dispensaries (This referred to all facilities from where patients access medicines): These include retail pharmacies, hospitals, health centers, dispensaries, county and sub-county hospitals, clinics, Maternity Homes, and treatment centres.

Level IV: Illegal outlets selling medicines outside the approved distribution system. Included Informal or unauthorized markets (open markets, stalls, and mobile medicine peddlers).

Level V: Virtual market: e.g., sales of medicines via the Internet. No sample was collected from this level

According to MRS Tool, risk levels are attributed to each level with the highest risk at level IV and the lowest at level I.

3.5 Selection of the Sampling Outlets

A stratified random sampling technique was used to identify the sampling outlets from the selected counties using the QPM medicines risk assessment tool (MRS).

Risks were assigned to facilities at the sub-county level of the counties to be surveyed based on the level I to V criteria above. The risk was assigned for the different levels with the highest risk at the levels where the medicines are dispensed to the patients with no regulatory oversight (Level IV and V).

3.6 Sample size

The sample size of medicines and/or facilities to sample was calculated using the Cochran formula.

The sample size formula was incorporated in the MedRS Tool, and it eventually computed the sample size taking into consideration the various risk factors. The MRS also randomized the facilities to be sampled. The actual number of samples to be collected however was adjusted based on the availability of resources, and logistical and practical considerations. Based on the analyses, a total of about 100 samples of Artesunate 30mg/60mg Injection, 100 samples of Artemether/Lumefantrine 20/120mg (6s) tablets, 70 samples of Oxytocin, and 100 Gentamicin samples were projected to be collected, as indicated in table 3 below:

Table 3 Number of samples targeted for collection

No.	**Product**	**Therapeutic category**	**Total # of samples**
1	Artesunate Inj 30/60mg	Antimalarials	100
2	Artemether 20mg+Lumefantrine 120 mg tablets 6s		100
Total			
3	Oxytocin injection 10i.u/5i. u	MNCH	70
4	Gentamycin 20 mg/2ml injection		100
Total			**370**

3.7 Substitution criteria

Sample facility substitution: The sample collectors were allowed to substitute samples in any of the following scenarios:

i) If the randomly selected sampling outlet was closed or inaccessible
ii) If the medicine was not available or the dispenser/seller was unwilling to offer
iii) If the available medicine in the outlet had less than six month's shelf life remaining.

iv) When the stocks available were limited and medicine was critical in saving patients' lives
v) When there was a possibility of not getting the necessary minimum quantity of medicines in the collection outlet.

Facility Substitution: Sample collectors were allowed to substitute sampling outlets by replacing the randomly selected sampling outlet with the nearest similar risk level facility found in the same stratum or category.

3.8 Definition of Sample

To ensure uniformity in the collection of medicines, it was necessary to define the attributes that determine a sample. For this survey, a sample comprised a given medicinal product with the same product name, the active ingredient, manufacturer, dosage form, unit dose (strength), batch/lot number, collection outlet, and packaging material.

3.8.1 Number of Units per sample

The survey was of public health interest and the principle of good laboratory practices for pharmaceutical quality control laboratories was followed. The number of dosage units per sample collected was to be sufficient to allow for:

i) Conducting the planned test
ii) Investigation and confirmatory testing for those out of specification (OOS)
iii) Retention samples to be used for retesting in the case of dispute

Table 4 Minimum required quantities of samples to be collected

Formulation/Dosage form	**Targeted quantity for collection**	**Minimum quantity that was collected**
Tablets	100 tablets	80 tablets
Ampoules	25 amp	15 amp

3.9 Sample Collection

3.9.1 Sample collection method

Two kinds of sampling techniques were used: overt and covert. The overt sampling technique was applied for all facilities except illegal outlets where a covert approach was applied.

3.9.2 Sample collection tools

The following tools were used during sample collection:

i) Sample collection form (*Annex I: Sample* **Collecting Form**)
ii) Sample information collection excel tool (Annex)

iii) Sufficient packaging, labelling, and transportation tools- Cold chain carriers/ containers + ice packs, Ziploc plastic bags, markers, pens, and pencils, masking tapes, temperature data loggers Sample packing Carton

3.9.3 Sample collection logistics:

The sample collectors used either land transport or air depending on the transportation system and accessibility of the sites in the country. The fieldwork activity took ten (10) days (18th – 27th August 2021) and was preceded by a two days training of the sample collectors at the PPB offices in Nairobi. The collected samples were shipped to pharmacy and poisons board offices for screening, and verification and subsequently to the National Quality Control Laboratory for confirmatory testing.

3.9.4 Sample Collection Instructions and Precautions

Every effort was made to collect samples in their original packages. For each sample collected the team filled and signed the sample collection form (Annex 1). This should be done after leaving the sampling site for covert sampling to avoid unnecessary suspicion and/or questions.

To avoid confusion, each sample was identified by a unique code number (A/B as indicated below) consisting of the name of the sample collection region/site and unique facility ID number from the MedRS tool:

i) The name of the region (The first three letters of the region, e.g., NAI for Nairobi
ii) Facility ID number assigned by the MedRS tool
iii) Product code (AL6, GENT, OXY5/OXY10, ART30/ART60)
iv) Three-digit sequential serial number i.e., 001, 002...

The following product details were indicated in the sample collection form and the sample information excel tool, for each sample collected.

i) Sample's unique code
ii) Product name (as applicable brand/trade name or generic name)
iii) Name of active ingredient
iv) Dosage form
v) Strength per administration unit (unit dose)
vi) Description of primary container
vii) Package size (number of administration units per package)
viii) Batch number/Lot Number
ix) Manufacturing date and expiry date
x) Name of manufacturer
xi) Country and address of manufacturing site
xii) Regulatory status in Kenya (i.e., authorized or not authorized for marketing)

xiii) Name, address, and contact of the healthcare facility where the sample is collected from
xiv) Name of County and sub-county
xv) Handling, shipping, and Storage of Samples

3.10 Sample Testing

Sample testing was performed in a stepwise manner using a risk-based testing approach as outlined in the *Guidance for Implementing Risk-Based Post-Marketing Quality Surveillance in Low- and Middle-Income Countries*.

This was conducted as detailed below.

Table 5 Proportion of sample testing per the three testing levels. We applied a risk-based testing approach, critical test attributes of confirmatory testing were considered in assessing the quality of collected samples following figure 2:

Figure 2 Risk-based compendial testing flow that was followed

Any sample that failed a test was investigated as per the laboratory's out-of-specification procedures. A certificate of analysis was prepared for each sample subjected to compendial analysis.

3.10.1 Compendia Used

Official compendia were used in the analysis of the samples as listed below.

a) British Pharmacopoeia (2019), The Stationery Office, London.
b) The International Pharmacopoeia (Ph. Int.), 10th Edition, 2020, World Health Organization.

3.10.2 Reagents and Solvents

All chemicals, reagents, and solvents used were of analytical grade and the highest purity as specified in the compendia listed above.

3.10.3 Chemical Reference Standards

Primary chemical reference substances obtained from the USP, Rockville, Maryland, USA, or, working chemical reference substances traceable to a primary chemical reference substance whenever possible were used in the quantitative tests.

3.10.4 Instrumentation

All testing equipment used was suitably calibrated and deemed appropriate for the testing required using internal standard operating procedures.

3.10.5 Sample Preparation

The sample and chemical reference standard solutions were freshly prepared for each analysis as outlined in the product monographs contained in the appropriate compendia listed above.

a) Analytical Tests

i. Consistency of Formulated Preparations

The Uniformity of Weight (Mass) test from the BP was used. All the artesunate/lumefantrine tablets were subjected to this test.

The test involved individually weighing 20 units taken at random; where the number of samples taken was insufficient 10 units were taken.

ii. Sterility

The test is applied to substances, preparations or articles that are required to be sterile. The test for sterility is carried out under aseptic conditions. The precautions taken to avoid contamination are such that they do not affect any micro-organisms which are to be revealed in the test. The working conditions in which the tests are performed are monitored regularly by an appropriate sampling of the working area and by carrying out appropriate controls. The basis of the sterility test, as a culture-based method, is as described in the harmonized pharmacopeias. The actual test involves either:

- Membrane Filtration Technique or.
- Direct Inoculation

The sample/media is then incubated for at least 14 days to facilitate any growth in the media at 30 – 35 °C for anaerobic and aerobic bacteria, and at 20 – 25 °C for fungi and molds in case any of these are present in the product.

iii. pH

iv. The test involved taking an appropriate volume of sample and determining its pH using a suitably calibrated electronic pH meter. The observed value was compared against the limits specified in the appropriate monographs.

This involved the determination of the amount of active ingredient in a pharmaceutical preparation expressed as a percentage of the stated amount. The sample and chemical reference substance preparation, the testing parameters and instrumentation were as specified in the appropriate monograph.

The amount of active ingredient in the sample was determined by comparing the response due to the sample solution to the response of the chemical reference substance solution whose concentration was known. The result was expressed as a percentage of the stated amount and compared against the limits specified in the appropriate monograph.

b) Reporting of Test Results

A Certificate of Analysis (CoA) incorporating a summary of the actual method used to test each sample and the results obtained were issued for each of the 65 samples tested. Each CoA has a unique certificate of analysis number with the format CAN/2021-22/###.

3.11 Verification of Regulatory Status

All collected samples were checked as to whether they were registered and retained by PPB or not. Both the registered products and unregistered products were sent to the laboratory for testing. Appropriate regulatory actions were applied for unregistered products and products not retained.

3.12 Data Analysis, Interpretation, and Dissemination

3.12.1 Data Quality Assurance

Data quality was assured through the provision of training to sample collectors and by using a standard sample collection form and through supervision of the sample and data collection process. All hard copies of recorded documents were compiled on MS excel, cleaned, and prepared for data analysis.

3.12.2 Data interpretation

Poor quality medicines may be degraded, substandard, or falsified. In this survey, the WHO's definition was used to classify medicines as "Substandard or Falsified medicine". The regulatory status of products was evaluated based on the PPB's internal procedure or policy.

4 Results

4.1 Samples

The RB PMS samples were collected from 17 counties across the country in as indicated below. The total number of samples collected was 285. Samples from two counties of Turkana and Mandera were collected during the IGAD PMS regional work and are still undergoing compendial testing.

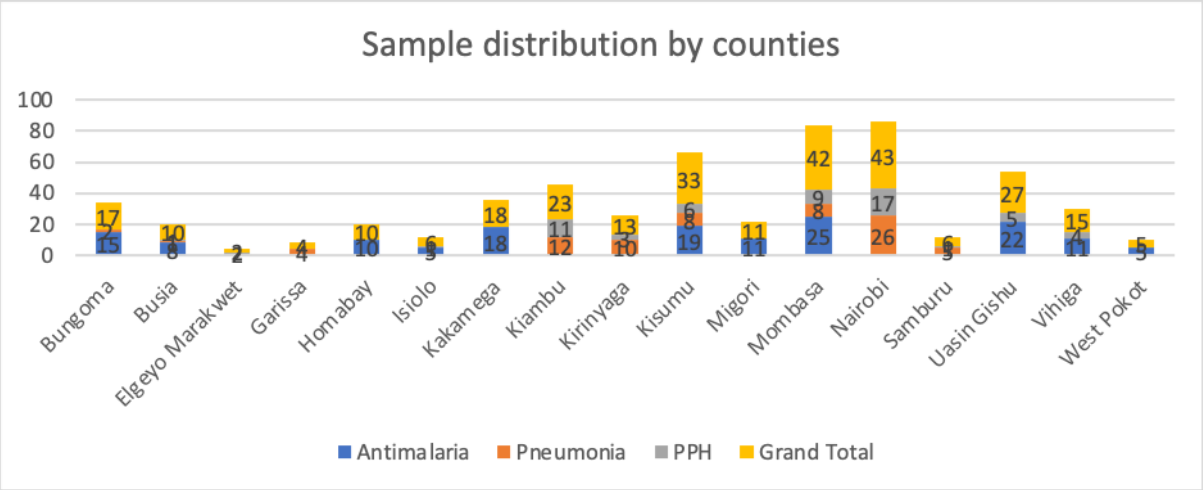

Figure 3 Distribution of collected samples by counties

Nairobi county had the highest number of samples at 43 followed by Mombasa at 42 and Kisumu County had 33 samples. The least number of samples were collected from Elgeyo Marakwet at 2, followed by Garissa with 4 samples, West Pokot with five and Isiolo and Samburu with six samples each. A total of 81 AL samples were collected across the country followed with 76 Gentamycin samples, 68 artesunate samples and 60 oxytocin samples. Uasin Gishu county had the highest number of AL samples at 14 followed with Mombasa County with 10 samples.

For Artesunate, Mombasa County had the highest number of samples at 15 followed with Kisumu with 10 samples. 26 gentamycin samples were collected from Nairobi followed with 12 samples from Kiambu. The highest number of oxytocin samples were collected from Nairobi at 17 followed with Kiambu that contributed 11 samples.

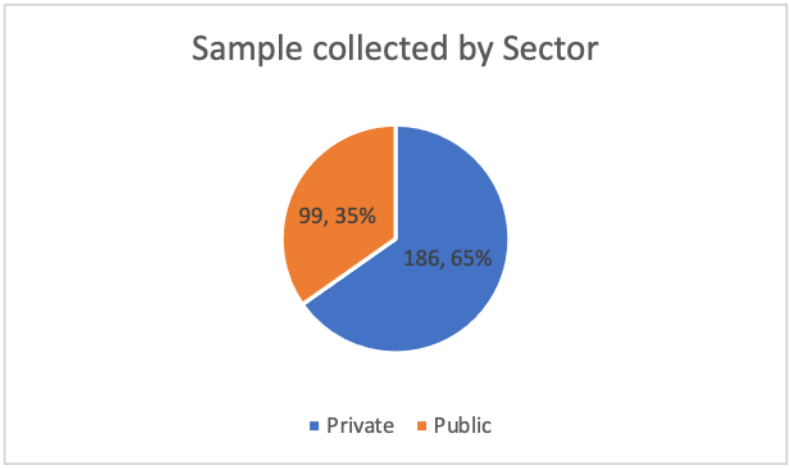

Figure 4 Distribution of collected samples by sector

Samples were collected from both the public and private sectors, where patients access medicines. 65% of the samples came from the private sector while 35% came from the public sector.

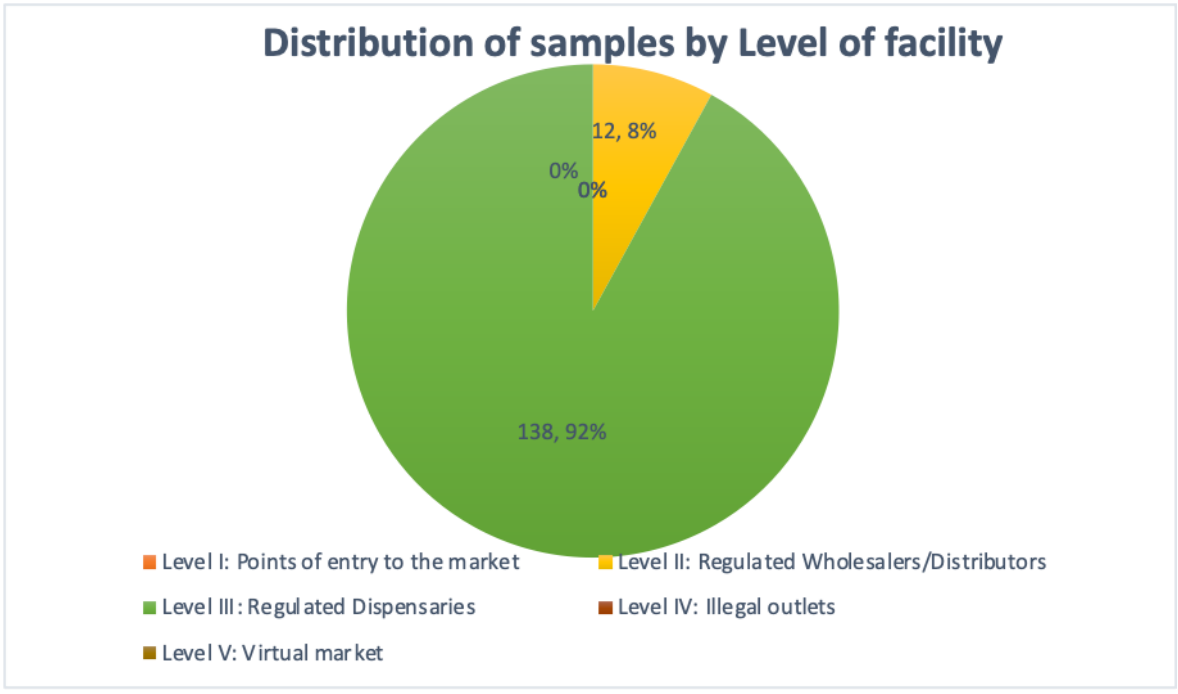

Figure 5 Distribution of collected samples by facility risk level

The majority of samples were collected from level III facilities. This class of facilities contributed 92% of all the samples collected. The remaining 8% of the samples came from level II facilities. There were no samples collected from Levels I, IV, and V facilities.

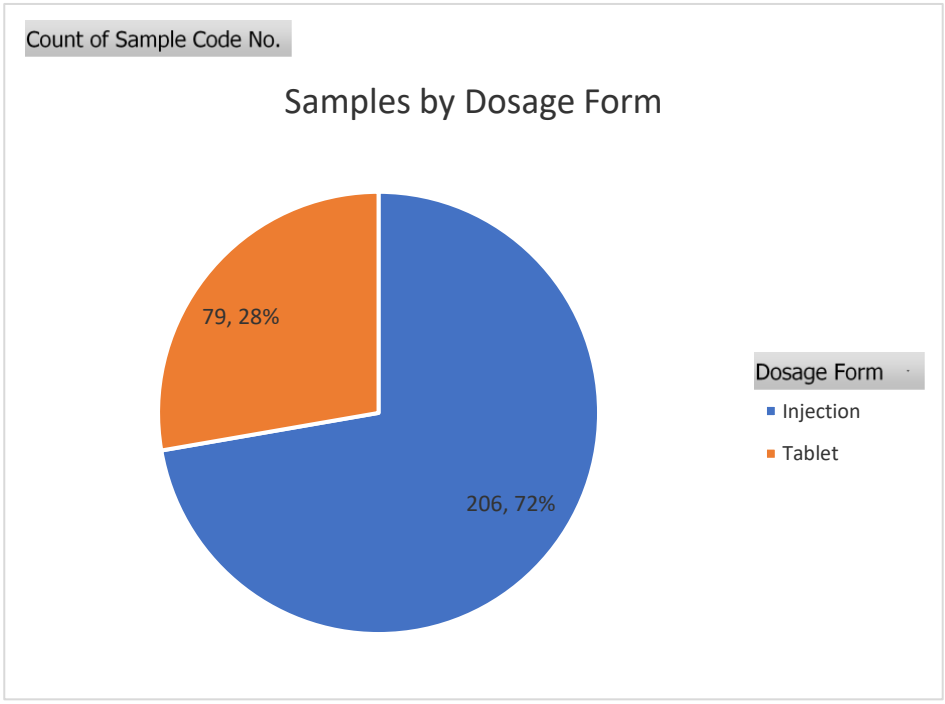

Figure 6 Summary of collected samples by dosage form

Majority of the samples that were collected from the filed were injection at 72%. The remaining 28% of the samples collected from across the country were tablets.

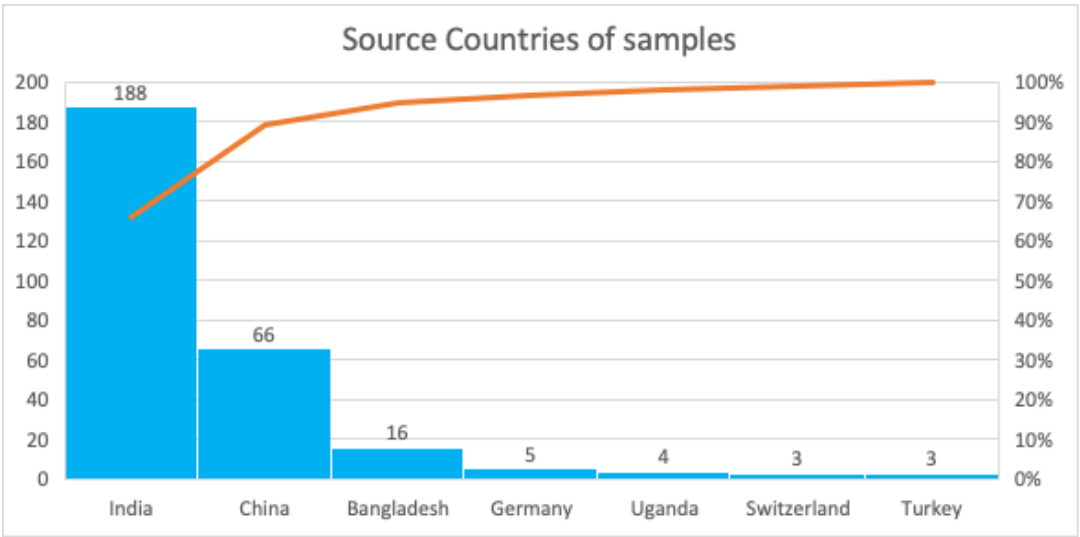

Figure 7 Source countries of samples collected from the field

Majority of the samples collected from the field were from India (188), China (66), and Bangladesh (16). These three countries contributed 94.7% of all the samples.

4.2 Registration status

The RB PMS collected a total of 54 unique brand products. Malaria samples were 23 (17 for AL and 6 for artesunate) brands while the RMNCH products were 31 (19 Gentamycin brands and 12 oxytocin brands) as seen below

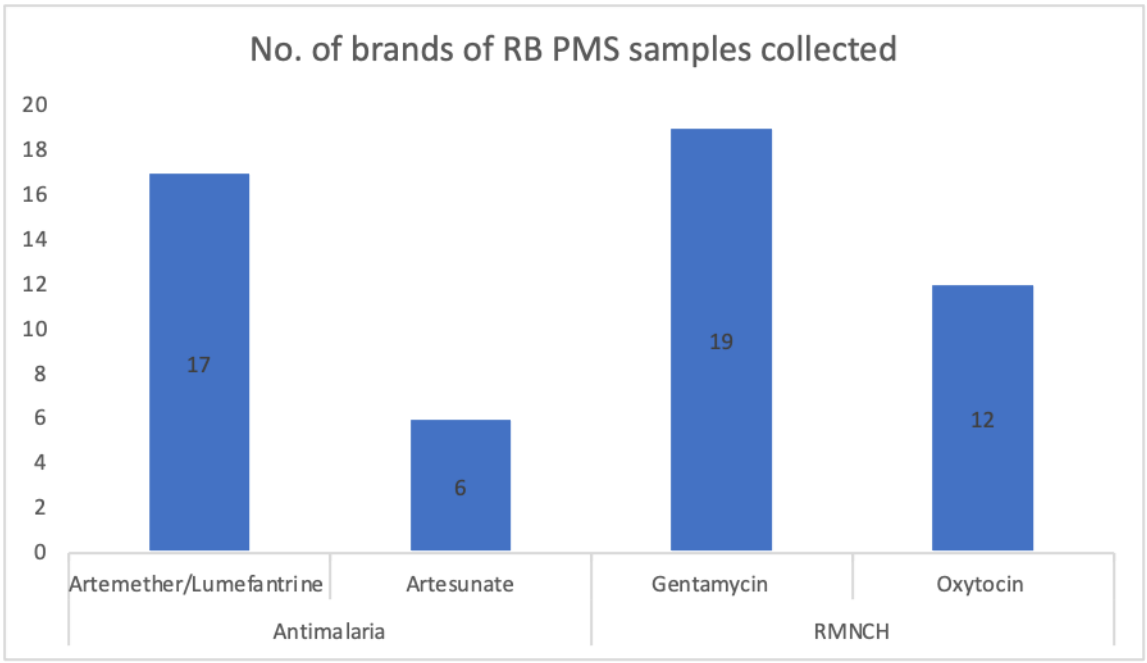

Figure 8 Number of brands collected from the field

4.3 Level 1 screening

Level one screening was conducted for all collected samples. The samples were taken through visual inspection.

Apart from two samples, all other samples complied with the legal labelling requirements. One sample, (Artemether and Lumefantrine Game Tablets 20/120) that did not meet the requirement had not included the site and address of the manufacturer on both secondary and primary packaging.

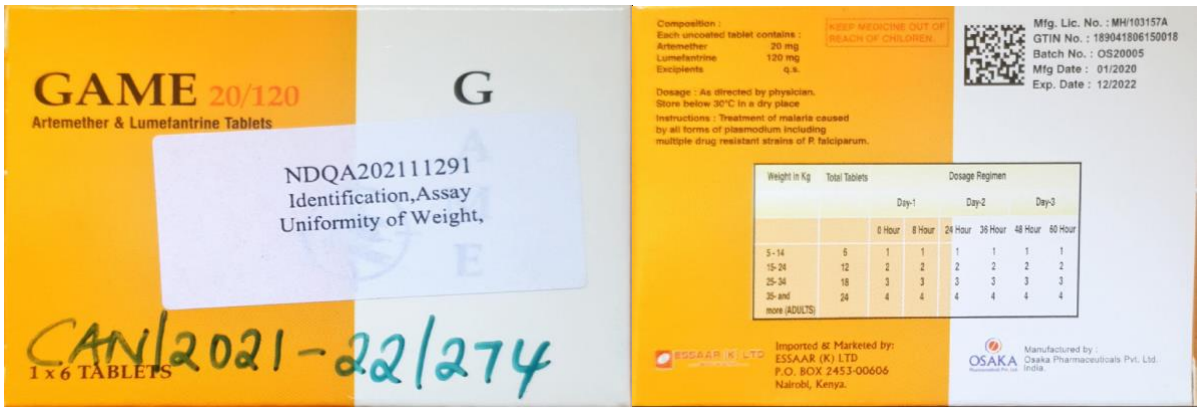

Figure 9 One of the samples that did not comply with PPB labelling requirements

Another sample, oxytocin (Oxytocin samples Vitocin 10IU) injection, indicated the temperature storage conditions on both the primary and secondary packaging material as 8 °C to 25 °C instead of the prescribed storage conditions of 2-8 °C.

4.4 Level II screening

Table 6 Summary of sample screening by Minilab®

Row Labels	Samples screened using Minilab®			Not screened using Minilab®	Total
	Pass	Doubtful	Failed		
Artemether/Lumefantrine	77	4	0	0	81
Artesunate	68	0	0	0	68
Gentamycin	0	0	0	76	76
Oxytocin	0	0	0	60	60
Total	**145**	**4**	**0**	**136**	**285**

A total 154 out of 285 samples were screened in the field through the use of Minilab®. All the Artemether/Lumefantrine and Artesunate samples were subjected to Minilab® screening and they all passed the Thin Layer Chromatography screening test. All Gentamycin and Oxytocin samples were sent to the laboratory directly without Minilab® screening.

4.5 Compendial testing

A total of sixty-two **(65)** drug products were submitted for compendial laboratory analysis (Table 7) on various days in October and November 2021.

Table 7 Distribution of drug products that were subjected to compendial testing

Formulated Drug Product	No of samples.
Artemether/Lumefantrine Tablets	20
Artesunate Injection	18
Gentamicin Injection	12
Oxytocin Injection	15
Total	**65**

The number subjected to compendial testing was determined based on the compliance status from level I and level II testing as well as the financial considerations. The samples were diversified by batch number, brand, and regional distribution.

An analysis request form was filled out for each of the samples selected for laboratory analysis. Each sample was assigned a unique laboratory reference number for ease of tracking.

4.6 Analysis of Samples

4.6.1 Tests performed

The four groups of medicines (AL, Gentamycin, Artemether, and Oxytocin) underwent different analyses depending on the drug sample formulation and the number of individual units available per sample. The table below summarises the different tests carried out on the samples.

Table 8 Compendial tests undertake

Formulated Drug Product	Tests Requested	Compendia
Artemether/Lumefantrine (AL) Tablets	Uniformity of Weight, Identification & Assay	Ph. Int. 2020 10th Edition
Artesunate IM/IV Injection	Sterility, Identification & Assay, pH	Ph. Int. 2020 10th Edition
Oxytocin Injection	Sterility, Identification, pH & Assay	BP 2019 Vol. III Page 1053
Gentamicin Injection	Sterility, Identification, pH & Assay	BP 2019 Vol III Page 685

4.6.2 Results of compendial testing

a) Sample Description

Artemether/Lumefantrine tablets were the majority of the sixty-five (65) samples at 20 (31%) samples, followed by Artesunate Injection at 18 (28%) samples, Oxytocin Injection at 15 (23%) samples, and Gentamicin Injection at 12 (18%) samples (Figure 10).

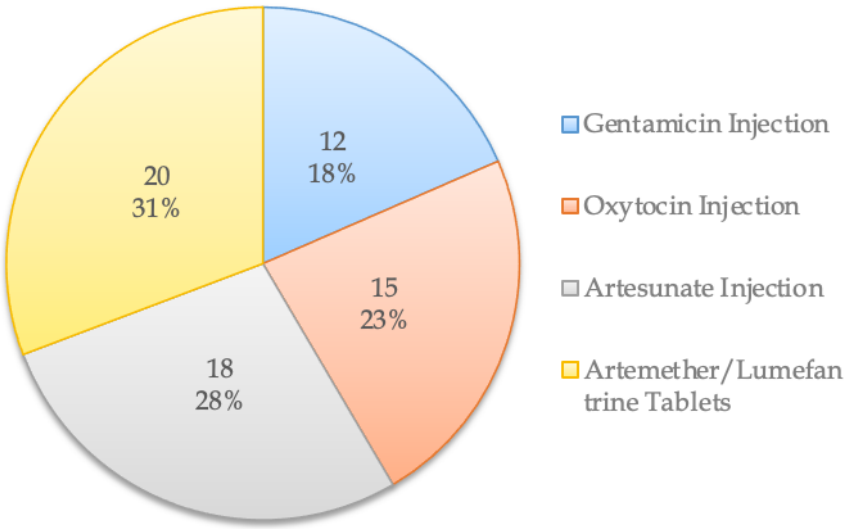

Figure 10 Sample Distribution for compendial testing samples

The samples tested at NQCL were collected from 17 different counties and are distributed as shown in Table 3 and Figure 2 below.

Table 9 Sample distribution of the compendial analysed sample by county

	County	AL	ART	GENT	OXY	Total
1.	Kisumu	1	4	2	2	**9**
2.	Uasin Gishu	4	2	0	2	**8**
3.	Mombasa	2	1	1	2	**6**
4.	Bungoma	1	3	0	0	**4**
5.	Busia	1	1	1	1	**4**
6.	Homabay	3	1	0	0	**4**
7.	Kakamega	2	2	0	0	**4**
8.	Kiambu	0	0	2	2	**4**
9.	Vihiga	2	1	0	1	**4**
10	Isiolo	1	1	0	1	**3**
11	Kirinyaga	0	0	2	1	**3**
12	Migori	2	1	0	0	**3**
13	Samburu	0	0	2	1	**3**
14	Nairobi	0	0	1	1	**2**
15	West Pokot	1	1	0	0	**2**
16	Elgeyo Marakwet	0	0	0	1	**1**
17	Garissa	0	0	1	0	**1**
18	**Total**	**20**	**18**	**12**	**15**	**65**

AL = Artemether/Lumefantrine, ART = Artesunate, GENT = Gentamicin, OXY = Oxytocin

Artemether lumefantrine were most samples at 20 followed by artesunate injection at 18, oxytocin at 15, and gentamycin at 12. The samples were from across the country as indicated in the map below (Figure 11)

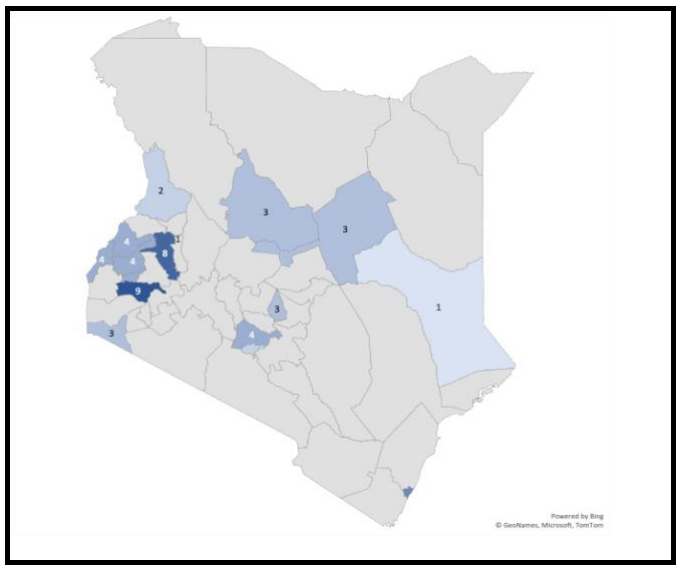

Figure 11 Distribution of compendial tested samples across the country

Kisumu county had the most samples of nine while the least number of samples analysed came from Elgeyo Marakwet and Garissa at one each.

Table 10 Sample distribution by facility risk level and facility sector type.

	Sector	Private	Public	Total
1.	Level II: Regulated Wholesalers/Distributors	4	0	**4**
2.	Level III: Regulated Dispensaries	32	29	**61**
	Total	**36**	**29**	**65**

Sixty-one (61) of the samples were collected from regulated dispensaries; either retail pharmacies, hospitals, health centres, dispensaries, county and sub- county hospitals, clinics, maternity homes, or treatment centres, thirty-two (32) of which were in the private sector while 29 were from the public sector. Four (4) samples were collected from regulated wholesalers or distributors, and all of these were from the private sector.

Table 11 Sample Distribution by Sector and API

	AL	ART	GENT	OXY	Total
Private	9	6	11	10	**36**
Public	11	12	1	5	**29**
Total	**20**	**18**	**12**	**15**	**65**

Thirty-six (36) of the samples were from the private sector and twenty-eight (29) from the public sector. In terms of API, artemether lumefantrine were 20 samples followed by artesunate at 18, oxytocin at 15 and gentamycin samples being 12.

The samples analysed originated from different countries as indicated below. Majority of the samples were from India and China who contributed a combined 91% of the total samples. Only one sample was manufactured in Africa

Table 12 Distribution of analysed products by country of manufacture

	Country	AL	ART	GENT	OXY	Total N (%)
1.	India	19	14	4	13	50 (77%)
2.	China	0	4	5	0	9 (14%)
3.	Bangladesh	0	0	3	0	3 (5%)
4.	Germany	0	0	0	1	1 (2%)
5.	Switzerland	0	0	0	1	1(2%)

	Country	AL	ART	GENT	OXY	Total N (%)
6.	Uganda	1	0	0	0	1(2%)
	Total	**20**	**18**	**12**	**15**	**65**

AL = Artemether/Lumefantrine, ART = Artesunate, GENT = Gentamicin, OXY = Oxytocin

b) Laboratory Analysis Results

i. Artemether and Lumefantrine Tablets

The artemether lumefantrine underwent analytical tests against the following specifications (Table 13).

Table 13 Artemether/Lumefantrine Tablets Test Specifications

TEST	METHOD	COMPENDIA	SPECIFICATION
Uniformity of Weight	Weight	BP 2019 Vol. V App. XII C	Not more than 2 tablets deviate by more than 5% from the mean tablet weight
Identification	HPLC	Ph. Int. 10th Edition	Chromatogram of the assay sample exhibit two peaks with R_T corresponding to the two principal peaks in the assay standard preparation
Assay	HPLC	Ph. Int. 10th Edition	90.0 – 110.0%

The artemether lumefantrine samples were analysed according to the above specifications from the British and International Pharmacopeia.

All the twenty (20) samples from eleven (11) different manufacturers complied with tests carried out of ID, uniformity of weight and assay. See Table 17

In terms of visual inspection, it was noted that Game tablets from Osaka Pharmaceuticals Pvt Ltd did not conform with the country's labelling requirements as tablet Samples did not have a Manufacture site and Address.

ii. Artesunate Injection

Artesunate injection samples underwent analytical tests against the following specifications (Table 14).

Table 14 Artesunate Injection Test Specifications

Test	Method	Compendia	Specification
Sterility	Membrane Filtration	BP 2019 Vol. V	No Microbial Growth

Test	Method	Compendia	Specification
		App. XVI A	
Uniformity of Dosage Units	Weight Variation	USP NF 2021	Acceptance Value (AV) not more than 15.0 %
Identification	HPLC	Ph. Int. 2020 10th Edition	Chromatogram of the assay sample exhibits a peak with R_T corresponding to the principal peak in the assay standard preparation
Assay	HPLC	Ph. Int. 2020 10th Edition	90.0 – 110.0%

All the eighteen (18) artesunate samples complied with the specifications as seen aboveTable 18. The samples were from four (4) different manufacturers. See Table 18

iii. Testing for pH for artesunate samples

Following market complaints received by the Division of National Malaria program and the Pharmacy and Poisons Board on lack of therapeutic effectiveness of a specific brand and batch of artesunate injection, the PPB and DNMP initiated investigations on the complaint. The investigation included collecting and testing of the complaint sample. The testing results showed the product failed to comply with PH specifications for reconstituted artesunate.

In view of the above, the investigation was extended to other products of artesunate injection from different manufacturers to check specifically compliance with PH specifications. The findings of the analysis can be seen in Table 19.

It is important to note that different manufacturers had different specifications for the pH values (6.0-8.0, 7.0-8.5) The results from the pH testing were varied and some did not comply with the manufacturer's specification.

From the above, PPB should request all the artesunate injection market authorization holders to harmonize their pH specifications to be based on the compendial pH specifications.

iv. Gentamicin Injection

The requested analytical tests were carried out to the following specifications (Table 15).

Table 15 Gentamicin Injection Test Specifications

Test	Method	Compendia	Specification

Sterility	Membrane Filtration	BP 2019 Vol. V App. XVI A	No Microbial Growth
Identification	TLC	BP 2019 Vol. III Page 685	R_F values of the three principal spots obtained with the sample preparation should be ± 5% of the R_F values of the three principal spots obtained with the standard preparation.
Acidity/ Alkalinity	pH	BP 2019 Vol. III Page 685	3.0 – 5.5
Assay	Disk Diffusion	BP 2019 Vol. III Page 685	97.0 – 110.0%

All twelve (12) samples complied with the test specifications as seen in Table 21 . The samples were from five (5) different manufacturers.

v. Oxytocin Injection

The requested analytical tests were carried out to the following specifications (Table 16).

Table 16 Oxytocin Injection Test Specifications

Test	Method	Compendia	Specification
Sterility	Membrane Filtration	BP 2019 Vol. V App. XVI A	No Microbial Growth
Identification	HPLC	BP 2019 Vol. III Page 1053	Chromatogram of the assay sample exhibits a peak with R_T corresponding to the principal peak in the assay standard preparation
Acidity/ Alkalinity	pH	BP 2019 Vol. III Page 1053	3.5 – 4.5
Assay	HPLC	BP 2019 Vol. III Page 1053	90.0 – 110.0%

All the fifteen (15) samples from nine (9) different manufacturers complied with the specifications (Table 20).

4.7 Regulatory actions

As a result of the RBPMS, the following regulatory actions were implemented.

1. The Pharmacy and Poisons Board wrote to the manufacturer of the artemether lumefantrine to update the labelling of his products as per

the product registration requirements. The labelling should include the complete address of the manufacturing site.

5 Discussion

The study involved collections of 285 samples of products that are used for treatment of malaria (n=150) and Reproductive, Maternal, New-born and Child Health (RMNCH) (n =135) collected from 17 counties in Kenya. Antimalarial samples collected included Artemether/lumefantrine tablets and artesunate injection while RMNCH samples included oxytocin and gentamicin. The largest number (n =150 or 52%) of the samples were collected in Nairobi (n =43), Mombasa (n=42), Kisumu (n = 33), Uasin Gishu (n = 27), and Kiambu (n =23) in that order. Majority (92.3%, n= 2630 of samples were collected from Level III regulated dispensaries, both private (n = 32) and public sector (n = 29), while the rest were collected from Level II regulated wholesalers and distributors. There were no samples that were collected in level 1 (points of entry to the market), Level IV (illegal outlets) and Level V (virtual market).

A total of sixty-five (65) drug products were submitted for compendial laboratory analysis. These products included AL tablets (n = 20), artesunate injection (n = 18), gentamicin injection (n = 12) and oxytocin injection (n = 15). Out of these 65 drugs products 50 (76.9%) were manufactured in India, 9 (13.8%) in China and the rest from Bangladesh (n=3), Germany (n = 1), Switzerland (n = 1) and Uganda (n =1). Seventy percent (70%) of the pharmaceutical products in Kenya are imported from other countries, particularly India (40%) and China (10%) [11, 12]. It was noted that none of the Kenyan manufacturers were involved in manufacturing of these products making the country to depend solely on imported products. This main reason for lack of locally manufactured products is that procurement of antimalarials in public sector depends on the funding from the Global Fund [13].

Apart from two samples, all other samples complied with the legal labelling requirements. One sample, the AL tablets, that did not meet the requirement had not included the site and address of the manufacturer on both secondary and primary packaging. Another sample, oxytocin injection, indicated the temperature storage conditions on both the primary and secondary packaging material as 8 °C to 25 °C instead of the storage conditions of 2-8 °C prescribed by the WHO [14] and an official circular of the PPB. It worth noting that a number of oxytocin injection products are available with the storage condition of below 25˚C and a shorter shelf-life, implying that, unlike those which recommend storage between 2-8˚C, these products are heat stable and can be stored under ambient conditions. Unfortunately, in tropics maintaining at temperatures below 25˚C is not easily attainable [15]. It is therefore recommended that all the

manufacturers must adhere to the PPB circulars and guidelines for labelling and storage of pharmaceuticals in the Kenyan market.

The major finding in this study was that all the sampled products met the compendial specifications for the content of the APIs. Previous surveys/studies have reported some cases of poor quality and falsified medicines [10]. The WHO estimated that 10% of medical products LMICs were either substandard or falsified. In Kenya, the prevalence of poor-quality medicines in the market was recorded as 4% in 2015. The quality of antimalarials between 2010-2016 in Kenya was found to be 3.6% [11]. A quality survey for oxytocin injection that was carried out in the IGAD region in 2019 showed that 20.9% of tested products did not meet quality specifications [12].

It was established that all AL tablets analysed complied with compendial specification limit of 90-110% for both artemether and lumefantrine content. However, the assays showed a wide range of variation of 91.1 - 109.7% for both ingredients with most brands generally, having lower content of lumefantrine than artemether. There were three brands whose lumefantrine and artemether were on the lower quantile. Generally, Artemether / Lumefantrine tablets that were sampled in the public sector showed significantly higher lumefantrine content than artemether which were sampled in the private sector.

Regarding the analysis of Artesunate Injection, the study established that all the eighteen (18) samples from the four manufacturers complied with the compendial specifications. The content of artesunate sodium in the product ranged from 98.9 - 104.5% (compendial limit 90-110%).

For gentamicin injection the twelve (12) samples that were collected from five (5) different manufacturers complied with the with the specifications. The content of gentamicin in the product ranged from 99.3 - 103.2% (compendial limit 97-110%). The pH of gentamicin solution in the product ranged from 3.4 – 5.2 (compendial limit 3.0 - 5.5).

For oxytocin injection the fifteen (15) samples that were collected from nine (9) different manufacturers complied with the with the specifications. The content of gentamicin in the product ranged from 100.7-108.2% (compendial limit 90-110%). The pH of gentamicin solution in the product ranged from 3.8 – 4.4 (compendial limit 3.5 - 5.5). Two of the samples indicated the temperature storage conditions on both the primary and secondary packaging material as 8 °C to 25 °C instead of the prescribed storage conditions of 2-8 °C.

6 Conclusion

The study concludes that the quality of antimalarial medicines Artesunate injection and Artemether/Lumefantrine tablets as well as oxytocin, and

gentamicin injections are of acceptable quality. There is a need for continuous monitoring of the products in the Kenyan market to ensure that they meet the market authorization requirements.

6.1 Survey limitations

1. Inaccessible facilities that had been selected by the MedRS tool
2. Lack of samples in some of the selected facilities

7 References

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8 Annexes

8.1 Annex I: Sample Collecting Form

	MINISTRY OF HEALTH PHARMACY AND POISONS BOARD
Sample information collecting form for quality survey of selected medicines circulating in Kenya	

Sample Unique code: _____

(Region name/Facility ID number/Product code/ serial number) (A/B/C/D e.g., KAK/2656/AL6/003)

Type of collection premise: Pri☐ ☐ublic:

Name of drug outlet sample was taken:
_____

Name of Sub- County _____ County
_____

Physical Address (Town, Building and Street)
_____

Tel. Number
_____

Email
Address_____
_

Product name (Brand name) of the sample:
_____

Name of active pharmaceutical ingredient(s) (INN) with strength:
_____

Dosage form (tablet, capsule, powder for injection, etc):
_____

Package size, type, and packaging material of the container (where applicable):
_____

Batch/lot number:
_____

Date of manufacture: _____ Expiry date:
_____

Name of the manufacturer:
_____

Address of manufacturer:
_____

Quantity collected (number of sample units or of multi-dose containers taken):
_____

Storage/climatic conditions at sampling site/point (temperature and humidity, indication of conditions during daytime only acceptable) and any other observations on storage

Where was the sample stored (Refrigerator, cabinet, shelf?)

Did the fridge have fridge thermometer?

Did they have temperature chart?

What was the temperature recording?
_____

Comments on suitability of premises where products are stored at sample collection site
_____

Abnormalities, remarks or observations that may be considered relevant, if any:
_____
_____

Date of sample collection:
_____

Name & Signature of sample collectors: Name & Signature of the supervisor

1._____ 1.
_____

2._____

Note:

Samples collected must remain in their original containers, intact and unopened.

This Sample Information Collection form should always be kept with the sample collected.

Proper sampling procedures should be followed.

The excel database should be properly filled

8.2 ANNEX III Compendial test results.

Artemether lumefantrine compendial testing results

Table 17 Artemether lumefantrine compendial testing results

	Sample reference number	Facility	County	Sector	Type	Product	Batch No.:	Manufacturer	Assay	
									A	L
1.	MOM/AL24/20.08.2021/019	Meditrust Healthcare Services	Mombasa	Private	Regulated Dispensaries	Shal'Artem Tablets	373431	Shalina Laboratories Pvt. Ltd	97.7 %	93.2 %
2.	VIH/AL24/23.08.2021/052	Mulundu Dispensary	Vihiga	Public	Regulated Dispensaries	Lumet Tablets	QK00962	CiplaQCIL	101.6 %	102.1 %
3.	UAS/AL18/23.08.2021/049	Chepkigen Health Centre	Uasin Gishu	Public	Regulated Dispensaries	Artefan 20/120 Tablets	PA0220C	Ajanta Pharma Limited	104.7 %	97.6 %
4.	KAK/AL6/20.08.2021/017	Shinyalu Health Centre	Kakamega	Public	Regulated Dispensaries	Lumartem DT Dispersible Tablets	ID01527	Cipla Ltd	105.4 %	98.1 %
5.	ISI/AL6/18.08.2021/010	Zen Pearl Holdings	Isiolo	Private	Regulated Dispensaries	Game 20/120 Tablets	OS20005	Osaka Pharmaceuticals Pvt. Ltd	98.1 %	91.1 %
6.	VIH/AL6/21.08.2021/031	Beluu Chemist	Vihiga	Private	Regulated Dispensaries	Game 20/120 Tablets	OS20005	Osaka Pharmaceuticals Pvt. Ltd	99.9 %	92.7 %
7.	HOM/AL12/20.08.2021/016	Kogweno Oriang Dispensary	Homabay	Public	Regulated Dispensaries	Lumerax DT 20/120 Tablets	FWR510031	Ipca Laboratories Ltd	98.7 %	98.6 %
8.	UAS/AL24/21.08.2021/043	St. Monica Pharmacy	Uasin Gishu	Private	Regulated Dispensaries	Lumiart-20 Tablets	BNT0421035	Brawn Laboratories Limited	104.1 %	98.7 %
9.	MIG/AL6/19.08.2021/026	Karungu Sub County Hospital	Migori	Public	Regulated Dispensaries	Artefan Dispersible 20/120 Tablets	PA0260C	Ajanta Pharma Limited	102.3 %	96.5 %
10.	BUN/AL6/18.08.2021/002	Cheptais Subcounty	Bungoma	Public	Regulated Dispensari	Lumiter Dt Tablets	NAD2087A	Oxalis Labs	101.8 %	99.8 %

	Sample reference number	Facility	County	Sector	Type	Product	Batch No.:	Manufacturer	Assay	
									A	L
		Hospital			es					
11.	KAK/AL24/20.08.2021/022	Bukura Health Centre	Kakamega	Public	Regulated Dispensaries	Artemether / Lumefantrine 20/120mg Tablets	HWE430456	Ipca Laboratories Ltd	96.4 %	96.4 %
12.	UAS/AL24/21.08.2021/042	Life Chek Family Pharmaceuticals	Uasin Gishu	Private	Regulated Dispensaries	Lumiart-20 Tablets	BNT0421036	Brawn Laboratories Limited	105.9 %	99.8 %
13.	HOM/AL24/20.08.2021/009	Kabodo Dispensary	Homabay	Public	Regulated Dispensaries	Combiart 20/120 mg Tablets	7243546	Strides Pharma Science Limited	109.7 %	100.7 %
14.	MIG/AL6/19.08.2021/001	Karungu Sub County Hospital	Migori	Public	Regulated Dispensaries	Artemether /Lumefantrine Dispersible Tablets	PA1389I	Ajanta Pharma Limited	103.5 %	100.1 %
15.	WES/AL6/24.08.2021/061	Paraywa Community Dispensary	West Pokot	Public	Regulated Dispensaries	Combiart-DT 20/120 mg Dispersible Tablets	7241430	Strides Shasun Limited	105.1 %	100.6 %
16.	BUS/AL6/24.08.2021/078	G.K. Prison Dispensary	Busia	Public	Regulated Dispensaries	Combiart-DT 20/120 mg Dispersible Tablets	7241436	Strides Shasun Limited	108.1 %	101.8 %
17.	HOM/AL24/20.08.2021/006	Akiliance Pharmacy	Homabay	Private	Regulated Dispensaries	Lonart Tablets	LRC634	Bliss GVS Pharma Ltd	99.8 %	96.8 %
18.	MOM/AL24/23.08.2021/043	Kahada Medical Clinic	Mombasa	Private	Regulated Dispensaries	Lonart Tablets	LRC656	Bliss GVS Pharma Ltd.	99.1 %	94.0 %
19.	UAS/AL24/21.08.2021	Lilly's Chemist	Uasin	Privat	Regulated	Lonart	LRC660	Bliss GVS	100.1	95.0

	Sample reference number	Facility	County	Sector	Type	Product	Batch No.:	Manufacturer	Assay	
									A	L
	/034		Gishu	e	Dispensaries	Tablets		Pharma Ltd.	%	%
20.	KIS/AL24/21.08.2021/021	Pharmaplus Pharmacies	Kisumu	Private	Regulated Dispensaries	Lonart Tablets	LRC664	Bliss GVS Pharma Ltd	101.1 %	94.3 %

A = Artemether, L = Lumefantrine

Artesunate injection compendial testing results

Table 18 Artesunate injection compendial testing results

	Sample Code	Facility	County	Sector	Type	Product Name	Batch No.:	Manufacturer	(Assay 90.0-110%)
1	UAS/ART60/23.08.2021/054	Burnt Forest Subcounty Hospital	Uasin Gishu	Public	Regulated Dispensaries	Larinate-60 for IV/IM Injection	GKW100117	IPCA Laboratories Ltd	102.9%
2	HOM/ART60/20.08.2021/010	Kabodo Dispensary	Homabay	Public	Regulated Dispensaries	Artesun 60 mg for IV/IM Injection	ZA1190510	Guilin Pharmaceutical Co. Ltd	101.8%
3	BUN/ART60/18.08.2021/004	ACK Butonge Dispensary	Bungoma	Private	Regulated Dispensaries	Larinate-60 for IV/IM Injection	JFQ020078	IPCA Laboratories Ltd	103.0%
4	KIS/ART60/24.08.2021/068	Muhoroni Sub-County Hospital	Kisumu	Public	Regulated Dispensaries	Artesun 60 mg for IV/IM Injection	ZA1190510	Guilin Pharmaceutical Co. Ltd	98.9%
5	UAS/ART60/23.08.2021/047	Uasin Gishu County Hospital	Uasin Gishu	Public	Regulated Dispensaries	Larinate-60 for IV/IM	GKW100117	IPCA Laboratories Ltd	104.5%

	Sample Code	Facility	County	Sector	Type	Product Name	Batch No.:	Manufacturer	(Assay 90.0-110%)
						Injection			
6	KIS/ART60/23.08.2021/061	Mediocare Pharmaceuticals Ltd	Kisumu	Private	Regulated Dispensaries	Malart-60 for IV/IM Injection	61887	Syncom Formulations (I) Ltd	99.1%
7	VIH/ART60/23.08.2021/059	Vihiga Private General Hospital	Vihiga	Private	Regulated Dispensaries	Gsunate 60 mg for I.M./I.V. Injection	IP20094	Indasi Lifescience Pvt. Ltd	99.5%
8	KAK/ART60/20.08.2021/023	Bukura Health Centre	Kakamega	Public	Regulated Dispensaries	Larinate-60 for IV/IM Injection	JFQ020080	IPCA Laboratories Ltd	100.3%
9	ISI/ART60/18.08.2021/009	Isiolo Nursing Home	Isiolo	Private	Regulated Dispensaries	Gsunate 60 mg for I.M./I.V. Injection	IP20093	Indasi Lifescience Pvt. Ltd	99.4%
1	BUN/ART60/18.08.2021/001	Marigo Dispensary	Bungoma	Public	Regulated Dispensaries	Larinate-60 for IV/IM Injection	JFQ020078	IPCA Laboratories Ltd	103.2%
1	BUS/ART60/24.08.2021/071	G.K. Prison Dispensary	Busia	Public	Regulated Dispensaries	Larinate-60 for IV/IM Injection	JFQ020079	IPCA Laboratories Ltd	102.6%
1	BUN/ART60/19.08.2021/011	Elgon View Hospital	Bungoma	Private	Regulated Dispensaries	Gsunate 60 mg for I.M./I.V. Injection	IP21038	Indasi Lifescience Pvt. Ltd	101.6%
1	MIG/ART60/19.08.2021/014	Boma Medicare Ltd	Migori	Private	Regulated Wholesalers	Gsunate 60 mg for I.M./I.V. Injection	IP20093	Indasi Lifescience Pvt. Ltd	99.0%

	Sample Code	Facility	County	Sector	Type	Product Name	Batch No.:	Manufacturer	(Assay 90.0-110%)
1	WES/ART60/24.08.2021/063	Kapenguria County Referral Hospital	West Pokot	Public	Regulated Dispensaries	Artesun 60 mg for IV/IM Injection	ZA1190708	Guilin Pharmaceutical Co. Ltd	101.1%
1	KAK/ART60/20.08.2021/028	Makunga Rural Demonstration Centre	Kakamega	Public	Regulated Dispensaries	Larinate-60 for IV/IM Injection	JFQ020080	IPCA Laboratories Ltd	101.9%
1	KIS/ART60/23.08.2021/043	Nyahera Subcounty Hospital	Kisumu	Public	Regulated Dispensaries	Larinate-60 for IV/IM Injection	JFQ020075	IPCA Laboratories Ltd	103.7%
1	KIS/ART60/23.08.2021/044	Nyahera Subcounty Hospital	Kisumu	Public	Regulated Dispensaries	Artesun 60 mg for IV/IM Injection	ZA1190510	Guilin Pharmaceutical Co. Ltd	99.6%
1	MOM/ART60/25.08.2021/056	Mbungoni Catholic Dispensary (CBHC)	Mombasa	FBO	Regulated Dispensaries	Larinate-60 for IV/IM Injection	GKW040061	IPCA Laboratories Ltd	101.0%

Table 19 pH Results of Artesunate injection samples

No.	Product	Batch No.	Manufacturer	Specification	pH
1.	GSUNATE 60 mg for I.M./I.V. Injection	ID20227	Indasi Lifescience Pvt. Ltd	7.0 - 8.5	7.9
2.	Larinate 60	GZV060054	IPCA Laboratories Ltd		8.3
3.	Larinate-60 for IV/IM Injection	GZV060044	IPCA Laboratories Ltd	6.0 - 8.0	7.9
4.	Malart-60 for IV/IM Injection	61888	Syncom Formulations (I) Ltd	-	7.9
5.	Artesun 60 mg for IV/IM Injection	T6190505	Guilin Pharmaceutical Co. Ltd	-	7.9
6.	GSUNATE 60 mg for I.M./I.V. Injection	ID20114	Indasi Lifescience Pvt. Ltd	7.0 - 8.5	8.0

No.	Product	Batch No.	Manufacturer	Specification	pH
7.	Artesun 60 mg for IV/IM Injection	T6190505	Guilin Pharmaceutical Co. Ltd	-	8.0
8.	Larinate-60 for IV/IM Injection	GZV060067	IPCA Laboratories Ltd	6.0 - 8.0	8.0
9.	Larinate-60 for IV/IM Injection	GZV060053	IPCA Laboratories Ltd	6.0 - 8.0	8.1
10.	Larinate-60 for IV/IM Injection	GZV060066	IPCA Laboratories Ltd	6.0 - 8.0	8.1
11.	Larinate-60 for IV/IM Injection	GZV060065	IPCA Laboratories Ltd	6.0 - 8.0	8.2
12.	Larinate-60 for IV/IM Injection		IPCA Laboratories Ltd	6.0 - 8.0	8.2
13.	Artesun 60 mg for IV/IM Injection		Guilin Pharmaceutical Co. Ltd	-	8.2
14.	Larinate-60 for IV/IM Injection	GZV060067	IPCA Laboratories Ltd	6.0 - 8.0	8.3
15.	GSUNATE 60 mg for I.M./I.V. Injection	ID20114	Indasi Lifescience Pvt. Ltd	7.0 - 8.5	8.3
16.	Artesun 60 mg for IV/IM Injection	T190605	Guilin Pharmaceutical Co. Ltd	-	8.3
17.	Larinate-60 for IV/IM Injection	GZV060066	IPCA Laboratories Ltd	6.0 - 8.0	8.5
18.	Larinate-60 for IV/IM Injection	GZV060027	IPCA Laboratories Ltd	6.0 - 8.0	
19.	GSUNATE 60 mg for I.M./I.V. Injection	ID20148	Indasi Lifescience Pvt. Ltd	7.0 - 8.5	

Oxytocin injection compendial testing results

Table 20 Oxytocin injection compendial testing results

	Sample Code	Facility	County	Sector	Type	Product Name	Batch No.:	Manufacturer	Assay (90.0 – 110.0%)	pH (3.5 – 4.5)
1	SAM/OXY/18.08.2021/002	Samburu County Referral Hospital	Samburu	Public	Regulated Dispensaries	Evatocin Injection 10 I.U/mL	0747	Neon Laboratories Limited	106.5%	3.9
2	BUS/OXY10/24.08.2023/080	G.K. Prison Dispensary	Busia	Public	Regulated Dispensaries	Oxymed Injection 10 IU/mL	1EB04161	Ciron Drugs & Pharmaceuticals Pvt. Ltd	108.2%	4

	Sample Code	Facility	County	Sector	Type	Product Name	Batch No.:	Manufacturer	Assay (90.0 – 110.0%)	pH (3.5 – 4.5)
3	UAS/OXY10/23.08/2021/055	Burnt Forest Subcounty Hospital	Uasin Gishu	Public	Regulated Dispensaries	Oxymed Injection 10 IU/mL	1EB03157	Ciron Drugs & Pharmaceuticals Pvt. Ltd	103.8%	4.4
4	KIS/OXY10/24.08.2021/063	Rachar Sugarbelt Nursing Home	Kisumu	Private	Regulated Dispensaries	Oxytocin Injection BP 10 IU/mL	0406	Umedica Laboratories Pvt. Ltd	108.2%	4.2
5	KIA/OXY10/20.08.2021/039	St. Mary's Mother and Child Hospital	Kiambu	Private	Regulated Dispensaries	Vitocin - 10 Injection	V20109	Vital Healthcare Pvt Limited	100.7%	4.2
6	ISI/OXY/18.08.2021/012	Galaxy Hospital Limited	Isiolo	Private	Regulated Dispensaries	Vitocin - 10 Injection	V20058	Vital Healthcare Pvt Limited	107.7%	4.1
7	VIH/OXY10/23.08.2021/053	Nidas Pharmaceuticals	Vihiga	Private	Regulated Dispensaries	Evatocin Injection 10 I.U/mL	0741	Neon Laboratories Limited	107.6%	3.9
8	KIA/OXY10/22.08.2021/052	Mary Help of The Sick Mission Hospital	Kiambu	Private	Regulated Dispensaries	Evatocin Injection 10 I.U/mL	0750	Neon Laboratories Limited	105.4%	3.9
9	ELG/OXY10/24.08/2021/059	Kapsowar Mission Hospital	Elgeyo Marakwet	Private	Regulated Dispensaries	Oxytocin Injection BP 10 IU/mL	0406	Umedica Laboratories Pvt. Ltd	104.0%	4.2
1	UAS/OXY10/23.08/2021/048	Chepkigen Health Centre	Uasin Gishu	Public	Regulated Dispensaries	Oxytocin Injection BP 10 IU/mL	KOEIE-001	Laborate Pharmaceuticals India Ltd	107.4%	3.8
1	NAI/OXY10/19.08.2021/017	Guru Nanak Hospital	Nairobi	Private	Regulated Dispensaries	Oxyzed 10 IU Injection	ML20079	Makcur Laboratories Ltd	101.4%	4.1
1	MOM/OXY/23.08.2021/032	Makadara Chemists-Meru Road	Mombasa	Private	Regulated Dispensaries	Oxytocin-10 Injection	00729A	Roteximedica GmbH Arzneimittelwerk	107.1%	4.0

	Sample Code	Facility	County	Sector	Type	Product Name	Batch No.:	Manufacturer	Assay (90.0 – 110.0%)	pH (3.5 – 4.5)
1	KIS/OXY10/23.08.2021/041	Victoria Healthcare Limited	Kisumu	Private	Regulated Wholesalers	Curtocin Injection	1EA04206	Ciron Drugs & Pharmaceuticals Pvt. Ltd	105.6%	4.0
1	MOM/OXY5/24.08.2021/054	Beyondscope Hospital	Mombasa	Private	Regulated Dispensaries	Syntocinon Injection 5 I.U.	SNP48	Novartis Pharma Stein AG	101.4%	3.9
1	KIR/OXY10/25.08.2021/070	Kerugoya County Referral Hospital	Kirinyaga	Public	Regulated Dispensaries	Oxyt Injection	KLOY0006	Kilitch Drugs (India) Ltd	107.1%	3.8

Gentamycin Sulphate injection compendial testing results

Table 21 Gentamycin Sulphate injection compendial testing results

	Sample Code	Facility	County	Sector	Type	Product Name	Batch No.:	Manufacturer	Assay (97.0 – 110.0%)	pH (3.0 – 5.5)
1	BUS/GENT80/24.08.2021/075	Jacmack Chemist	Busia	Private	Regulated Dispensaries	Gentamycin Sulphate Injection BP	200410	Shandong Xier Kangtai Pharma Co., Ltd	99.3%	5.2
2	KIA/GENT80/20.08.2021/035	Mayan Lifestyle Chemists	Kiambu	Private	Regulated Dispensaries	Redgenta - 80 Injection	V20099	Vital Healthcare Pvt. Ltd	102.0%	5.0
3	KIR/GENT80/25.08.2021/078	Modesty Pharma Ltd	Kirinyaga	Private	Regulated Dispensaries	Mycin Injection	152001	Neon Laboratories Limited	100.9%	4.0
4	SAM/GENT80/17.08.2021/004	Al-Abrar	Samburu	Private	Regulated	Genacyn 80	ODO2560	Square	101.2%	3.8

	Sample Code	Facility	County	Sector	Type	Product Name	Batch No.:	Manufacturer	Assay (97.0 – 110.0%)	pH (3.0 – 5.5)
		Drugmart			Dispensaries	Injection		Pharmaceuticals Ltd		
5	KIS/GENT80/23.08.2021/030	Kentons Ltd	Kisumu	Private	Regulated Wholesalers	Gentamycin Sulphate Inj BP	200410	Shandong Xier Kangtai Pharma Ltd	101.7%	5.2
6	KIR/GENT80/25.08.2021/073	Kerugoya Prime Chemist	Kirinyaga	Private	Regulated Dispensaries	Gentamycin Sulphate Injection 80mg/2mL	203212148	Reyoung Pharma Co. Ltd	103.2%	5.1
7	GAR/GENT80/19.08.2021/014	Alliance Medical Centre	Garissa	Private	Regulated Dispensaries	Gentamycin Sulphate Injection 80mg/2mL	203212146	Reyoung Pharmaceutical Co. Ltd	100.2%	5.1
8	MOM/GENT80/21.08.2021/022	Ace Nothern Hospital	Mombasa	Private	Regulated Dispensaries	Redgenta - 80 Injection	V20175	Vital Healthcare Pvt. Ltd	100.5%	5.1
9	NAI/GENT80/23.08.2021/064	Nairobi South Hospital	Nairobi	Private	Regulated Dispensaries	Gentamycin Sulpahte Inj 80mg/2mL	QD6200507	Guilin Pharma Co. Ltd	100.7%	5.3
1	KIS/GENT20/24.08.2021/069	Muhoroni Sub-County Hospital	Kisumu	Public	Regulated Dispensaries	Genacyn 20 Injection	9KO2351	Square Pharmaceuticals Ltd	100.9%	3.4
1	SAM/GENT20/18.08.2021/005	Al-Abrar Nursing Home	Samburu	Private	Regulated Dispensaries	Genacyn 20 Injection	OCO1190	Square Pharmaceuticals Ltd	100.9%	3.8
1	KIA/GENT80/22.08.2021/053	Gatuma-Ini Wholesale Pharmacy	Kiambu	Private	Regulated Wholesalers	Intamycin 80 Injection	KLIN0003	Kilitch Drugs (India) Ltd	101.7%	3.5

8.3 Sample Collection Checklist

Before starting the sample collection exercise from the sites, please ensure you have planned for all the following.

No.	Activity	Time frame	Responsible person	
1.	Clearance by National Medicine Regulatory Authority			
2.	Sampling Forms			
3.	Sampling Tools: MS Excel Sheet			
4.	Sampling Tools: Sample Storage and Transporting Container			
5.	Sampling Tools Indelible markers Indelible pens			
6.	Sampling Tools: Sampling Adhesive tapes			
7.	Sampling Tools: New dedicated notebook (*Please use one new notebook per sampling team*)			
8.	Logistic planning: local transportation to sites including sample collection site map.			
9.	Logistics: Money for Purchasing of Samples			
10.	Logistics: Accommodation			
11.	Logistics: Other incidentals			
12.	Logistics: A Global Position Device or a Smart Phone. Photo of the Sample Collection Exercise			
13.	Inventory of Minilab® and compendial lab supplies			