MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

REPORT OF THE RISK-BASED POST-MARKETING SURVEILLANCE OF MATERNAL, NEONATAL AND CHILD HEALTH PRODUCTS AND TECHNOLOGIES IN THE KENYAN MARKET IN SEPTEMBER 2024

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EXECUTIVE SUMMARY

The Pharmacy and Poisons Board, in collaboration with the Ministry of Health and the National Pharmacovigilance/Post-Marketing Surveillance Technical Working Group (PV/PMS TWG), and with the support from the Gates Foundation, successfully implemented a routine proactive post-marketing surveillance for Maternal, Neonatal and Child Health (MNCH) Products.

Samples were collected from Pharmaceutical Wholesalers, Retail pharmacies, and Healthcare facilities at National, County, and Sub-County levels across the country as determined by the Medicines Risk based Surveillance (MedRS) tool. A total of 213 samples underwent screening, which involved a review of product information, visual and physical inspection of the products. Out of the total samples collected 85 were subjected to Minilab testing, and 94 samples were analyzed through compendial testing at the Pharmacy and Poisons Board (PPB) Quality Control Laboratory and Mission for Essential Drugs and Supplies (MEDS) Laboratory.

One product exhibited doubtful results following physical/visual inspection and Minilab screening. Furthermore, 89.4% of the samples subjected to compendial testing complied with all the specifications for the test parameters analyzed.

Monitoring of the quality of HPTs in the Kenyan market is essential for ensuring their safety and efficacy, ultimately leading to better patient outcomes and enhancing public confidence in the healthcare system.

Dr. Fred Siyoi

Chief Executive Officer

ACRONYMS & ABBREVIATIONS

AMR	Antimicrobial resistance
HPTs	Health Products and Technologies
IGAD	Intergovernmental Authority on Development
IPC	Infection Prevention and Control
LMICs	Low- and middle-income countries
MedRS	Medicines Risk-based Surveillance
MEDS	Mission for Essential Drugs and Supplies
MMR	Maternal mortality ratio
MNCH	Maternal, neonatal, and child health
NQCL	National Quality Control Laboratory
OOS	Out of Specification
ORS	Oral rehydration salts
PPB	Pharmacy and Poisons Board
PPH	Post-partum hemorrhage
PV/PMS TWG	Pharmacovigilance and Post-Marketing Surveillance Technical Working Group
PvERS	Pharmacovigilance Electronic Reporting System
QSE	Quality, safety, and efficacy
SDGs	Sustainable Development Goals
SF	Substandard and falsified
UHC	Universal Health Coverage
VKDB	Vitamin K deficiency bleeding
WHO	World Health Organization

DEFINITION OF TERMS

Falsified health product or health technology	A product that is deliberately and fraudulently mislabeled with respect to identity, composition and /or source.
Post-marketing surveillance (PMS)	All the processes that are carried out to continuously track/monitor quality, safety and efficacy of medicines in the market (after registration)
Proactive PMS	Coordinated surveys, sampling and analysis, evaluation and assessment of regulatory requirements in relation to labeling, storage etc.
Reactive PMS	Follow up on complaints from spontaneous reporting
Substandard Health product or health technology	Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both.

ACKNOWLEDGEMENTS

The Pharmacy and Poisons Board and the National Pharmacovigilance/Post-marketing Surveillance Technical Working Group (PV/PMS TWG) express their sincere gratitude to the Kenyan Ministry of Health, Gates Foundation, United States Pharmacopeial Convention, the National Quality Control Laboratory, County Governments, and the Mission for Essential Drugs and Supplies. We gratefully acknowledge all individuals and organizations that contributed to the post-marketing surveillance (PMS) of maternal, neonatal, and child health products and technologies including the development of the PMS protocol, compendial testing, data analysis, and report writing. We also extend our appreciation to the dedicated sample and data collectors whose efforts were key to the success of this survey, as well as to the outlets that supported sample collection.

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ABSTRACT

Background: The United Nations, through the World Health Assembly, affirms the centrality of maternal, neonatal and child health (MNCH) in socioeconomic development. Sustainable Development Goal 3 (SDG 3) aims at minimizing maternal, neonatal, and child mortality by eliminating deaths arising from preventable and treatable conditions. Kenya's maternal mortality ratio stood at 355 per 100,000 live births in 2019, while neonatal and under-five mortalities were 21 and 41 per 1,000 live births annually, respectively. These indicators are unacceptably higher than the respective SDG 3 targets, and several interventions should be instituted to strengthen standards of care in MNCH. One of the strategic interventions is ensuring that the MNCH products meet the requisite Quality, Safety, and Efficacy (QSE) attributes.

Objective: To conduct a risk-based post-marketing surveillance (PMS) of health products and technologies in the Kenyan market used in maternal, neonatal, and child health.

Methods: This survey utilized a descriptive cross-sectional study design with quantitative methods for data collection, which took place in September 2024. The MedRS tool guided HPT and facility selection based on MNCH disease prevalence and potential public health risks such as quality and safety history of the HPTs. Sample size was calculated using the Cochran formula integrated within the MedRS tool. Samples were collected across the various levels of the supply chain. Samples were subjected to Physical/ visual Inspection, Minilab™ screening and Compendial testing at the Pharmacy and Poisons Board (PPB) Quality Control Laboratory, and the Mission for Essential Drugs Supplies (MEDS) laboratory.

Results: A total of 213 samples were collected from 136 facilities; public (46), private (87), and faith-based (3) health facilities distributed in 37 counties. Forty-three (43) facilities monitored both temperature and relative humidity, 33 facilities were monitoring temperature only while 60 facilities were not

monitoring storage conditions. Twenty-six (26) out of the 32 facilities where Oxytocin was sampled from monitored refrigerator temperature. The storage temperature for Oxytocin was noted to be out-of-range (2-8^{0}C) in six (6) facilities, with the temperature ranging from -0.2^{0}C to 33^{0}C.

Out of 58 brands sampled, 47 brands (81%) were found to be registered as per the PPB database. One (1) sample exhibited doubtful results during visual inspection and Minilab™ screening. Of the 94 samples subjected to compendial tests, 84 (89.4%) complied with compendial specifications, eight (8) yielded inconclusive results and two (2) were noncompliant. The two noncompliant samples were Oxytocin and Kemoxyl DT.

Conclusion: This PMS identified two non-compliant products and 11 unregistered brands in circulation, highlighting regulatory and supply chain vulnerabilities. All non-compliant and unregistered products were subjected to regulatory action. Strengthening product registration enforcement, cold chain monitoring, and facility-level storage practices is recommended to safeguard the quality of MNCH products and improve health outcomes.

1. INTRODUCTION

1.1 Background

Health products and technologies (HPTs) are vital commodities in the prevention, control, and management of diseases, and preservation of well-being. To fulfil their intended therapeutic use, the HPTs should conform to the set compendial attributes for quality, safety and efficacy (QSE). The World Health Organization (WHO) estimates that 10.5% of HPTs in the pharmaceutical markets of low- and middle-income countries (LMICs) are either substandard or falsified (SF). A 2017 report by the WHO global surveillance and monitoring system for substandard and falsified medical products estimated that one in ten medicines, vaccines, and diagnostics in LMICs fail to meet compendial specifications for QSE[1]. The high prevalence of SF products in the LMICs has been attributed to weak technical capacity, ineffective pharmaceutical governance, and poor supply-chain management[2].

The United Nations Sustainable Development Goal (SDG) Target 3.8 specifically highlights the necessity for "access to safe, effective, quality, and affordable essential medicines and vaccines for all" as the cornerstone of Universal Health Coverage (UHC). Health products and technologies that consistently meet QSE attributes are critical for efficient disease management and promote public confidence in healthcare systems. On the contrary, SF products are a major impediment to achievement of optimal treatment outcomes and retard attainment of UHC. They not only cause treatment failure and adverse reactions, but also increase morbidity and mortality, and contribute to the development of antimicrobial resistance (AMR)[3]. Poor-quality HPTs also increase healthcare costs for both patients and the health system, wasting resources that could otherwise be used to benefit public health. Unfortunately, vulnerable populations, such as geographically marginalized communities, individuals at the bottom of the socioeconomic pyramid, and

[1] World Health Organization, WHO global surveillance and monitoring system for substandard and falsified medical products. Geneva: World Health Organization, 2017. https://apps.who.int/iris/handle/10665/3267
[2] Ozawa S, Evans DR, Bessias S, Haynie DG, Yemeke TT, Laing SK, Herrington JE. Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries: A Systematic Review and Meta-analysis. JAMA Netw Open. 2018 Aug 3;1(4):e181662. doi: 10.1001/jamanetworkopen.2018.1662. PMID: 30646106; PMCID: PMC6324280.
[3] Tegegne AA, Feissa AB, Godena GH, Tefera Y, Hassen HK, Ozalp Y, Suleman S. Substandard and falsified antimicrobials in selected east African countries: A systematic review. PLoS One. 2024 Jan 26;19(1):e0295956. doi: 10.1371/journal.pone.0295956. PMID: 38277385; PMCID: PMC10817106.

patients with comorbidities are at greater risk of SF products. Due to gendered inequities, mothers, neonates, and children are regarded as potentially vulnerable special populations[4] requiring a specialized healthcare delivery provision, aptly named maternal, neonatal, and child health (MNCH).

Maternal, neonatal, and child health is the health service provided to mothers, neonates, and children. Maternal health refers to the health of women during pregnancy, childbirth, and the postpartum period. Coverage of health services for most MNCH areas, including immunization, integrated management of newborn and childhood illnesses, antenatal care, and family planning, has consistently increased over the years.

In 2023, an estimated 260,000 women died from pregnancy- or childbirth-related causes globally, equivalent to one woman every two minutes[5]. Notably, nearly 70% of these deaths occurred in sub-Saharan Africa. On the other hand, 2.3 million neonates and 4.8 million children under five years died in 2023, translating to 6,500 neonates and 13,100 children dying every day[6]. Improving the provision of MNCH is therefore a global priority, whose goal is to make affordable and effective HPTs available to the women and children who need them most, thereby reducing morbidity and mortality due to preventable and treatable conditions[7].

The most common causes of maternal morbidity and mortality are post-partum haemorrhage (PPH), eclampsia, maternal sepsis, and anaemia[8], while asphyxia, pneumonia, neonatal sepsis, bacterial eye infections, vitamin K deficiency bleeding (VKDB), and diarrhea are the major causes of neonatal and child mortality[9]. Postpartum haemorrhage refers to excessive bleeding after childbirth and is the primary cause of approximately 20% of all global

[4] Sule FA, Uthman OA, Olamijuwon EO, Ichegbo NK, Mgbachi IC, Okusanya B, Makinde OA (2022). Examining vulnerability and resilience in maternal, newborn and child health through a gender lens in low-income and middle-income countries: a scoping review. *BMJ Glob Health* 7(4): e007426. DOI: 10.1136/bmjgh-2021-007426.
[5] Langlois EV, Reid A, Khosla, R (2025). Mothers deserve better: evidence-based strategies to address maternal mortality. *The Lancet Global Health.* DOI: 10.1016/ S2214-109X(25)00149-4.
[6] Neonatal mortality - UNICEF DATA
[7] PQM+. 2021. Guidance Document for Developing and Implementing a Risk-based PMS Program for maternal, neonatal, and Child Health Products Submitted to the U.S. Agency for
International Development by the PQM+ Program. Rockville, MD: U.S. Pharmacopeial Convention.
[8] Cresswell, Jenny A et al. (2025). Global and regional causes of maternal deaths 2009–20: a WHO systematic analysis. *The Lancet Global Health 13*(4): e626–e634.
[9] Decades of progress in reducing child deaths and stillbirths under threat, warns the United Nations.

maternal deaths[10]. The HPTs commonly used in the prevention and treatment of PPH include oxytocin injection, tranexamic acid, and magnesium sulphate.

Anaemia is common during pregnancy and is characterized by a deficiency of red blood cells and can have serious consequences for both the mother and the baby. Haematinics, which typically include iron and folic acid supplements, are essential in the prophylaxis and treatment of anaemia. In cases where preterm birth is anticipated, improving foetal lung maturity is crucial to reduce the risk of respiratory distress syndrome in the newborn. Dexamethasone, a corticosteroid, is administered to pregnant women at risk of preterm delivery. It helps accelerate the development of the baby's lungs, increasing the chances of survival and reducing the need for neonatal intensive care.

Surgical site infections resulting from childbirth can lead to maternal sepsis, a life-threatening condition that requires prompt treatment. Metronidazole is an antibiotic that is effective against anaerobic bacteria commonly involved in surgical site infections. This medicine is essential and helps eliminate the infection, thereby preventing the spread of sepsis and reducing the risk of severe complications.

Gentamicin sulphate is an aminoglycoside antibiotic critical in the management of neonatal sepsis. Additionally, alongside amoxicillin, gentamicin is useful in treating pneumonia, a common respiratory infection in children. Dispersible tablets of amoxicillin are especially useful in paediatrics, as they can be easily dissolved thus making administration easier and ensuring proper dosage.

Vitamin K deficiency bleeding is a serious condition in neonates and infants that can lead to uncontrolled bleeding. Vitamin K is administered prophylactically as an injection shortly after birth to ensure proper blood clotting and reduce the risk of bleeding complications in newborns. Diarrhoea is a common and potentially life-threatening condition in young children and

[10] Say L, Chou D, Gemmill A, Tunçalp Ö, Moller AB, Daniels J, Gülmezoglu AM, Temmerman M, Alkema L (2014). Global causes of maternal death: a WHO systematic analysis. *Lancet Glob Health 2*(6): e323-333. DOI: 10.1016/S2214-109X(14)70227-X.

can lead to dehydration and electrolyte imbalances. Oral rehydration salts (ORS) combined with zinc supplementation is the standard treatment for diarrhea. The ORS helps replenish lost fluids and electrolytes, while zinc shortens the duration of the illness and improves the child's recovery.[11] Although not among the common causes of neonatal ailments and mortality, conjunctivitis can occur in newborns and requires prompt treatment to prevent complications. Tetracycline eye ointment is used for the prophylaxis and treatment of these infections.

1.2 Problem Statement

Substandard and falsified HPTs jeopardize public healthcare delivery and compromise treatment outcomes, leading to economic losses of between $10 billion and $200 billion annually through ineffective treatment, emergence and spread of AMR, and increased occurrence of adverse events, contributing to increased morbidity and mortality. Therefore, implementing a robust and targeted PMS system is vital to mitigate SF risks and protect public health in priority health areas such as MNCH. [12]

A systematic review by Torloni et al. conducted in 2020 revealed that in many healthcare systems in poor-resource settings, SF essential medications are frequently encountered including those for MNCH.[13] High prevalence of SF products for MNCH is believed to be among the contributing factors to the ongoing high rates of severe complications and fatalities resulting from PPH, eclampsia, and sepsis in the LMICs[6]. The meta-analysis by Torloni et al. further indicated that nearly half (48.9%) of all uterotonic drugs sampled failed quality assessments. One in seven injectable antibiotic samples and 1 in 29 magnesium sulphate samples were of poor quality. The study also looked at differences in quality of medicines between the private and public sector and found that higher failure rates were generally in the private sector. This finding underlines the crucial need for both the national procurement

[11] https://www.ghsupplychain.org/
[12] Ozawa S, Evans DR, Bessias S, Haynie DG, Yemeke TT, Laing SK, Herrington JE. Prevalence and Estimated Economic Burden of Substandard and Falsified Medicines in Low- and Middle-Income Countries: A Systematic Review and Meta-analysis. JAMA Netw Open. 2018 Aug 3;1(4):e181662. doi: 10.1001/jamanetworkopen.2018.1662.PMID: 30646106; PMCID: PMC6324280.
[13] Torloni MR, Bonet M, Betran AP, Ribeiro-do-Valle CC, Widmer M (2020). Quality of medicines for life-threatening pregnancy complications in low- and middle-income countries: A systematic review. *PLoS ONE* 15(7): e0236060. https://doi.org/10.1371/journal.pone.0236060.

bodies and private providers to procure medications that adhere to WHO prequalification, or similar stringent requirements[6].

Previous PMS studies in Kenya and regionally have demonstrated significant variations in the quality of oxytocin along the supply chain, likely contributing to compromised treatment outcomes for PPH. A PMS of oxytocin injection within the Intergovernmental Authority on Development (IGAD) region in 2019 showed that 20.9% of tested products did not meet QSE specifications, with 13.6% of oxytocin samples collected in Kenya failing requisite compendial tests[14]. Similar findings were reported by Ammerdorffer et al. who assessed the quality of oxytocin and tranexamic acid HPTs in Kenya, Tanzania, Nigeria, and South Africa[15]. In this study, although all the eight oxytocin injection products sampled from the Kenyan market complied with the test for identity and assay, three (38%) products were non-compliant with the acceptance criteria for related substances, making them substandard.

A PMS conducted in 2021 for oxytocin injection samples collected from facilities near cross-border areas within the IGAD region gave 100% compliance with the compendial tests performed[16]. Despite this compliance, the PPB through the Pharmacovigilance electronic reporting system (PvERS) received 18 market complaints from 16 facilities regarding the therapeutic ineffectiveness of oxytocin injection between 2022-2024[17].

A recent report by the Kenyan Ministry of Health indicated that the three leading direct causes of maternal mortality during the 2021-2022 and 2022-2023 fiscal years were PPH, eclampsia, and sepsis, in that order. In the two fiscal years, PPH contributed 35% and 37% of deaths, while eclampsia caused 17% and 22% mortality, respectively. This shows that preeclampsia disorders are not identified early or are not managed correctly to prevent progression to eclampsia. Conversely, there was no change in the number of deaths due to sepsis, remaining 12% in both study periods. Puerperal sepsis mostly points

[14] Oxytocin study WHO, 2010; IGAD, June 2019.
[15] Ammerdorffer A, Rushwan S, Timms R, et al. Quality of oxytocin and tranexamic acid for the prevention and treatment of postpartum hemorrhage in Kenya, Nigeria, South Africa, and Tanzania (2022). *Int J Gyneco Obstet. 158* (Suppl. 1): 46-55. DOI:10.1002/ijgo.14197.
[16] Oxytocin study IGAD,2021
[17] pv.pharmacyboardkenya.org.

to the breach of Infection Prevention and Control (IPC) measures in both maternity wards and operating theatres, including management of early and prolonged rupture of membranes. On the other hand, the major causes of perinatal deaths in the two fiscal years were asphyxia (19%, 17%), low birth weight (LBW) (12%, 13%), neonatal sepsis (10%, 11%), and congenital anomalies (10%, 11%), respectively[18].

1.3 Justification

Maternal, neonatal and child health is one of the key cornerstones of socioeconomic development. The United Nations, through SDG Targets 3.1 and 3.2, has set enviable aspirations of reducing maternal, neonatal, and child mortality by 2030. SDG Target 3.1 aims to reduce the global maternal mortality ratio (MMR) to less than 70 per 100,000 live births, while SDG Target 3.2 aspires "to reduce neonatal mortality to at least as low as 12 per 1,000 live births and under-five mortality to at least as low as 25 per 1,000 live births."[19]

According to the Kenya National Bureau of Statistics, Kenya's MMR stood at 355 per 100,000 live births from the 2019 national census, translating to approximately 4,200 maternal deaths annually[20]. Further, neonatal and under-five mortalities are still unacceptably high at 21 and 41 per 1,000 live births annually[21], respectively. On a positive note, however, a modelling by the United Nations Maternal Mortality Estimation Inter-Agency Group estimates that the MMR in Kenya as of 2023 was 149 per 100,000 live births[22]. Although the MMR still exceeds the SDG Target 3.1, the reduction in maternal deaths has been credited to increased uptake of antenatal and prenatal care, and health facility child births, which more than doubled from a low of 39% in 2003 to 88% as of 2022. This implies that apart from promoting healthcare utilization during pregnancy and childbirth, several other concerted interventions should be instituted to strengthen standards of care in MNCH for Kenya to attain the two ambitious SDG Targets 3.1 and 3.2.

[18] Ministry of Health Kenya 2024: National Annual Maternal and Perinatal Death Surveillance and Response. Second Report. February 2024, Nairobi.
[19] Targets of Sustainable Development Goal 3.
[20] Kenya National Bureau of Statistics, 2020. *The 2019 Kenya Population and Housing Census Reports.*
[21] Kenya National Bureau of Statistics, 2023. *Kenya Demographic and Health Survey, 2022.*
[22] Maternal mortality ratio (modeled estimate, per 100,000 live births) - Kenya | Data.

One of the strategic interventions is ensuring that the MNCH products at the disposal of new mothers, neonates and children are not only affordable, but more critically meet requisite QSE parameters.

Considering the central role played by HPTs in case management and preservation of health, there is a compelling need to continuously implement targeted PMS of HPTs for MNCH to monitor the quality of HPTs and weed out SF products that could otherwise compromise treatment outcomes and wellbeing of mothers and their babies. Consequently, while applying the Medicines Risk-based Surveillance (MedRS) tool, this PMS addressed the HPTs essential in the management of diseases with substantial impact on MNCH, namely oxytocin injection, iron & folic acid tablets, dexamethasone injection, metronidazole injection, gentamicin injection, amoxicillin dispersible tablets, tetracycline eye ointment, vitamin K neonatal injection, ORS, and zinc sulphate tablets.

1.4 Objectives

1.4.1 General objective

This study aimed to conduct a risk-based post-marketing surveillance of priority health products and technologies in the Kenyan market used in safeguarding maternal, neonatal, and child health.

1.4.2 Specific objectives

This PMS:

1. Applied Medicines Risk-based Surveillance tool to identify regions and health facilities in Kenya for sampling of prioritized HPTs for MNCH.
2. Assessed the storage conditions of the prioritized MNCH products.
3. Established the registration status of priority MNCH products.
4. Assessed compliance of priority HPTs used in MNCH with requisite specifications for quality, safety, and efficacy, through physical and visual inspection, MiniLab testing, and compendial analysis.
5. Recommended implementation of appropriate regulatory actions based on the findings of this PMS.

2. METHODOLOGY

2.1 Surveillance Scope and Duration

The risk-based PMS covered different tiers of healthcare facilities drawn from the public, faith-based, and private sectors. The sampling sites included the wholesalers, retail pharmacies, and healthcare facilities at National, County, and Sub-County levels across the country as determined by the Medicines Risk-based Surveillance (MedRS) tool.

The data and sample collection activity was implemented for a period of seven days (7) in September 2024. The MiniLab screening and compendial testing activities were implemented between October and November 2024.

2.2 Survey design

This was a descriptive cross-sectional survey using quantitative data collection methods.

2.3 Selection of HPTs

The selection of HPTs for the PMS was based on the survey objective and potential public health impact through the use of risk factors. The risk factors were scored using the MedRS tool and included the following:

- Safety and quality history of the product (prior PV or HPT quality information, from PPB database)
- Stability of HPTs
- Manufacturing complexity
- GMP compliance
- Distribution chain complexity
- Extent of population exposure
- Patient vulnerability
- Dosage form complexity
- Therapeutic risk
- Extent of harm due to poor quality

- Availability of the HPT during the survey period
- Extent of distribution and use of the HPT in the region

2.4 Priority list of HPTs

Table 2.1 gives a summary of disease areas and HPTs selected for sampling and testing.

Table 1 List of disease areas and HPTs selected for sampling and testing

S/No	Disease areas/Indication	HPTs
1.	Postpartum hemorrhage, Induction and augmentation of labour	Oxytocin Injection
2.	Anaemia prophylaxis and treatment	Haematinics (Iron & Folic acid) tablets
3.	Improvement of fetal lung maturity	Dexamethasone 4mg/ml injection
4.	Maternal sepsis (Surgical site infections)	Metronidazole 5mg/ml injection
5.	Pneumonia, neonatal sepsis	Gentamicin 20 mg/ml injection
6.	Pneumonia	Amoxicillin 250mg dispersible tablets
7.	Prophylaxis and management of bacterial eye infections	Tetracycline Eye Ointment 1%
8.	Prophylaxis and treatment of vitamin K deficiency bleeding (VKDB) in neonates and infants.	Vitamin K 2mg/0.2mL
9.	Diarrhoea	ORS-Zinc (Co-pack)

2.5 Selection of survey sites

The selection of survey sites was determined by the MedRS tool. The tool was applied to determine the risk ranking of counties (regions), sub-counties, and sampling facilities for each of the HPTs selected.

Disease prevalence served as a key factor in determining geographical areas for the focused PMS activities. Regions with higher rates of MNCH-related diseases, such as pneumonia, postpartum haemorrhage, maternal and neonatal sepsis, anaemia, and diarrhea, were identified as priority areas.

The following factors were taken into consideration when selecting the sampling sites;

a) Areas where product complaints had been reported previously
b) Geographical location: Proximity to ports of entry
c) Areas where disease prevalence and indications are high
d) Areas with poor accessibility to products
e) Areas with high population density and low income
f) Areas with high probability of SF HPTs

All 47 counties were assessed using the MedRS tool; however, only 41 were selected to participate in the PMS activity. Six (6) counties, Mandera, Samburu, Elgeyo Marakwet, Isiolo, Marsabit, and West Pokot, were not selected during randomization. Among the 41 selected counties, sample collection was conducted in 37. In the remaining four (4) counties, Turkana, Nyamira, Lamu and Tana River, sample collection was not carried out due to insufficient samples and inaccessibility of some facilities.

2.6 Sampling levels

Sample collection was done at different levels within the drug distribution chain, as shown in Box 1. Risk levels were attributed to each level, with the highest risk at level V and lowest at level I (Nkansah P et al., 2017).

Table 2 Sampling and risk levels

Level I: Points of entry to the market
Warehouse of importers/ manufacturers, central and regional medical stores, NGO central stores, Procurement centers, and other facilities supplied directly within various programs, central wholesalers, and/or distributors.
Level II: Regulated retailers
Wholesalers/distributors, wholesale pharmacies and other regulated wholesalers.
Level III: Regulated dispensaries
Retail pharmacies, hospitals, health centers, sub-health centers, district hospitals, Clinics, Maternity Homes, community health workers, treatment centers.
Level IV: Virtual Outlets
Level V: Unauthorized outlets

2.7 Selection of sampling outlets

A stratified random sampling technique was used to identify the sampling outlets from the selected sampling sites. Using the MedRS tool, risks were assigned to facilities at the County level to be surveyed based on the facility level. 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. However, Level IV and V facilities were not included in this survey. The facilities were then stratified and randomly selected to ensure that 88representative outlets were selected for the survey. The outlets randomly identified are shown in Annexes 1, 2, 3, 4, 5, and 6.

2.8 Calculation of Sample Size

The sample size of medicines and/or facilities to sample was calculated using Cochran formula (Equation 1):

$$n = \frac{n_o}{1 + \frac{n_o - 1}{N}}$$

$$n_o = \frac{Z^2 p(1-p)}{e^2}$$

Where:

P is the prevalence of the poor HPTs, that is estimated percent of the HPTs that are believed to be of poor quality (it is an estimate of the true value). This value is based on historical data, market intelligence or other information. Without any prior knowledge, P= 0.5 will give the most conservative estimate of the sample size (largest).

The critical value (Z) is the confidence level or the risk of rejecting null hypothesis about the true prevalence of poor medicines. Z(CI) is 1.96(95%), 1.64(90%) and 1.28(80%) confidence level.

The sample size formula is incorporated in the online MedRS Tool, which eventually computes the sample size taking into consideration the various risk factors. The MedRS tool also randomizes the facilities to be sampled. The

actual number of samples to be collected however will be adjusted based on the availability of resources, and logistical and practical considerations. The number of samples collected per HPT is summarized in Table 2.2.

Table 3 Number of samples per HPT

S/N	Molecule	Formulation	Proposed No. of Samples	No. of samples collected
1.	Oxytocin	Injection	20	52
2.	Iron & Folic acid	Tablet	20	22
3.	Dexamethasone	Injection	20	22
4.	Metronidazole	Injection	20	22
5.	Gentamicin	Injection	20	23
6.	Amoxicillin dispersible	Tablets	20	19
7.	Tetracycline eye ointment	Ointment	20	17
8.	Vitamin K 0.2mg injection	Injection	20	10
9.	Oral rehydration salt Zinc Co-pack	Packs	20	26
	Total Samples		**200**	**213**

2.9 Substitution Criteria

2.9.1 Sample facility substitution

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

1. If the randomly selected sampling outlet is closed or inaccessible
2. If the medicines are not available or the dispenser/seller is unwilling to offer
3. If the available medicine in the outlet had less than six months' shelf life remaining.

4. When the stocks available is limited and medicine is critical in saving patients' lives
5. When there is a possibility of not getting the necessary minimum quantity of medicines in the collection outlet.

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.

2.10 Definition of a sample

To ensure uniformity in the collection of samples, a sample was defined as being composed of a given health product or technology with the same product name, active ingredient, manufacturer, dosage form, unit dose (strength), batch/lot number, collection outlet, and packaging material.

2.10.1 Number of units per sample

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

1. Conducting the planned screening and compendial testing;
2. Investigation and testing for those out of specification (OOS);
3. Retention samples are to be used for retesting in the case of dispute.

The minimum number of samples required for the survey for each medicine is given in Table 2.3.

Table 4 Minimum quantity of samples per medicine

S/N	Medicine	Required Quantity
1.	Amoxicillin Dispersible Tablets	60 Tablets
2.	Iron/Folic	60 Tablets
3.	ORS	40 sachets
4.	Zinc tablets	60 tablets
5.	Metronidazole Injection	10 bottles

S/N	Medicine	Required Quantity
6.	Oxytocin Injection	30 ampoules
7.	Gentamicin Injection 20mg/40mg/ml	30 ampoules
8.	Dexamethasone Injection	30 ampoules/vials
9.	Vitamin K 2mg/0.2mL Injection	50 Ampoules
10.	Tetracycline Eye Ointment	10 tubes

2.11 Sample collection

Samples were collected from each of the selected outlets by a team of appointed sample/data collectors. Prior to the fieldwork, a one-day training workshop was conducted for the personnel participating in the sample and data collection and the analysts for the Minilab activity. The participants received training on the data and sample collection tools, the protocol, and the quality survey, which included sampling techniques, sample handling, data entry, data management, and MiniLab methods.

The sample collection team at each site performed the following functions:

a. Collection of the samples from the selected outlets.
b. Replacement, where applicable, of samples collected to ensure there were no stock outs of selected products as a result of sampling activity.
c. Packing and labelling of samples collected in accordance with packaging and labeling instructions.
d. Completed the sample collection form for each sample.
e. Shipping samples to the MiniLab sites or quality control laboratory accordingly.

2.11.1 Sample collection tools

The following tools were used for sample collection.

1. Sample collection form (Annex 1: Sample Collection Form)
2. Facility form (Annex 2: Facility Details Form)
3. Oxytocin sample collection form (modified) (Annex 3: Oxytocin Sample Collection Form)

4. Product information review form (Annex 4: Product Information Review Form)
5. Excel Aggregation tool
6. Packaging, labeling, transportation and storage tools- (Cold chain carriers/containers + ice packs, Ziploc plastic bags, envelopes, markers, pens and pencils, masking tapes, temperature data loggers, and Sample packing cartons.)

2.11.2 Sample collection logistics

Samples were collected from each of the identified sampling outlets. The sample collectors used either land or air transport depending on the accessibility of the sampling sites. The field activity was implemented over a period of seven (7) days, followed by MiniLab activity for six (6) days. The samples were shipped to PPB-QCL and MEDS quality control laboratory for compendial testing as soon as possible where required.

2.11.3 Sample Collection instructions and precautions

Every effort was made to collect samples in their original packaging. For each sample collected, the team filled and signed the sample information collection form and facility details form (Appendix 2 and 3, respectively).

To avoid confusion, each sample was identified by a unique code (A/B/C/D as indicated below) consisting of the county code, name of the molecule, date of sample collection and sequential serial number of the sample e.g., NBI/GNT/27.08.2024/005 as indicated below

A: County code (as per gazette notice; e.g., NBI for Nairobi)
B: Product code (e.g., GNT for Gentamicin Injection)
C: Date of sample collection (e.g., 27.08.2024)
D: Three-digit sequential number of the sample. (e.g., 005)

For oxytocin samples collected in same healthy facility but different areas, the labeling was done as follows; NBI/OXY/P or M/27.08.2024/005 as indicated below
A: County code (as per gazette notice; e.g., NBI for Nairobi)

B: Product code (e.g., OXY for oxytocin Injection)

C: sampling area e.g., P-pharmacy in all facilities, M-maternity.

C: Date of sample collection (e.g., 27.03.2024)

D: Three-digit sequential number of the sample. (e.g., 005)

In addition:

- Each sample container/package was labeled with the unique sample code. The sample labeling was done at the time of collection to avoid mix-up.
- Samples collected had at least six (6) months remaining to expiry. Expired products were not sampled.
- The HPT labels and package leaflets were not removed or damaged.
- Sampling was recorded using sample collection form (Annex 1) and facility form (Annex 2) for each sample collected; and the Excel database specifically designed for this survey. Whenever the required information was not available, it was indicated in the appropriate space on the sample information collecting form.
- Samples collected were packed individually in special packaging materials together with the completed sample collection form.
- The samples were collected and kept/stored under the manufacturer's recommended storage conditions.

The details of the samples collected were also indicated. These included the following product details for each of the sample collected.

- Sample unique code
- Product name (as applicable brand/trade name or generic name)
- Name of active ingredient
- Dosage form
- Strength per unit dose
- Package size (number of administration units per package)
- Batch number/Lot Number
- Manufacturing date and expiry date
- Name of manufacturer
- Country and address of manufacturing site

2.11.4 Handling, shipping and storage of cold chain products

Collected samples were packed, transported and stored in such a way as to prevent any deterioration, contamination, or adulteration. They were stored and transported in their original sealed containers, according to the manufacturer's storage instructions.

Appropriate measures and adequate care were taken to ensure that samples reached the test site – whether for Minilab or confirmatory testing – without any physical or chemical damage. All containers were sealed and labeled appropriately. The samples were consistently kept in proper environmental conditions.

Oxytocin injection samples were protected from light and stored at a temperature of 2°-8°C and the temperature recorded from the time of collection until testing using data loggers. Precautions were taken to ensure that cold chain storage of oxytocin injections was not broken at any point during sampling, storage at the collection site and during transportation to the testing laboratory.

After completion of the sample collection activity, the sample collection team filed a field summary report using the standard format (Annex 6).

2.12 Secondary Sampling

Once all samples were received at the PPB QC laboratory, secondary sampling was carried out considering the diversity of product brands, batches, and regions where the products were collected.

Two hundred (200) samples of HPTs were targeted for collection from the selected facilities. Following fieldwork activity, two hundred and thirteen (213) HPT products were sampled based on availability. Eighty-five (85) out of the 213 collected samples were subjected to minilab (this consisted of products with minilab methods). Ninety-four (94) samples were subjected to compendial testing at PPB and MEDS QC laboratories.

Below is a summary of the samples collected and how they were subjected to analysis.

Table 5 Summary of Samples Analyzed

Disease Area	**Classification**	**Samples Collected**	**Minilab Samples**	**Compendial Samples**
Postpartum hemorrhage, Induction and augmentation of labour	Oxytocin Injection	52	-	23
Anaemia prophylaxis and treatment	Haematinics (Iron & Folic acid) tablets	22	-	17
Improvement of fetal lung maturity	Dexamethasone 4mg/ml injection	22	22	4
Maternal sepsis (Surgical site infections)	Metronidazole 5mg/ml injection	22	22	7
Pneumonia, neonatal sepsis	Gentamicin 20 mg/ml injection	23	23	5
Pneumonia	Amoxicillin 250mg dispersible tablets	19	18	4
Prophylaxis and management of bacterial eye infections	Tetracycline Eye Ointment 1%	17	-	12
Prophylaxis and treatment of vitamin K deficiency bleeding (VKDB) in neonates and infants.	Vitamin K 2mg/0.2mL	10	-	8
Diarrhoea	ORS-Zinc (Co-pack)	26	-	14
	Total	**213**	**85**	**94**

2.13 Laboratory analysis of samples

2.13.1 Levels of analysis

The analysis of samples adopted a risk-based, three-level testing approach. Level I was visual and physical inspection and product information review, which was done at the sample collection site. Level II was MiniLab testing conducted at two sublevels: Level IIA screening of samples at the PPB regional offices using MiniLab and Level IIB involved verification of MiniLab results at the PPB quality control laboratory. Level III was confirmatory testing, conducted using compendial methods at the PPB and MEDS quality control laboratories. The testing assessed specific test parameters determined by the National PV/PMS TWG and guided by the official compendia. For non-conforming samples, the PPB made efforts to implement regulatory actions based on established procedures, guidelines, policies, and regulations.

2.13.1.1 Level I: Visual, physical inspection and product information review

All collected samples were subjected to the following tests: physical/visual (P/V) inspection (registration status, expiry, product packaging, etc.) and product information review, which entailed inspection of the patient information leaflets and other literature inserts. The data was filled in the Post Marketing Surveillance Screening form (Annex 5: Visual and physical inspection and MiniLab results form)

2.13.1.2 Level IIA: MiniLab screening

This level involved undertaking the disintegration test and Thin-Layer Chromatography (TLC) using the Minilab. The test results for each sample were recorded on the Basic Tests Analysis Form by the analysts at the PPB regional offices. Once the screening was finalized, all samples with their respective forms attached (Sample Collection Form and Basic Tests Analysis Form) and TLC plates were stored and archived at the PPB according to the internal policy documents and procedures.

Molecules tested using Minilab methods include:

1. Amoxicillin Dispersible Tablets
2. Dexamethasone Injection
3. Gentamicin Injection
4. Metronidazole Injection

2.13.1.3 Level IIB: Verification Testing

The verification testing was conducted by repeating basic tests on the samples previously tested at Level IIA that failed or had a doubtful result. The results were recorded for each sample on the Basic Tests Analysis Form. The samples that failed or were doubtful after verification and 20% of the passed samples were subjected to confirmatory testing.

A sample was classified as:

Passed if it conformed to all product information and Minilab tests.

Failed if it did not conform to at least one of the three tests.

Doubtful if there were conflicting or inconclusive results for at least one of the three tests.

2.13.1.4 Level III: Confirmatory Testing with Compendial Analysis

This level of testing was carried out at the QC laboratories (PPB and MEDS). The protocol provided that the following criteria be applied while selecting samples for confirmatory/ compendial analysis:

(a) 100% of the samples that failed MiniLab screening.

(b) 100% of samples with doubtful MiniLab screening results.

(c) 20% of samples which passed MiniLab screening tests.

(d) Samples that lack MiniLab methods

Priority for compendial analysis was given to samples with:

1. Evidence of tampering (blurred prints, deceptive sealing, smudged with markings, etc.
2. Evidence of damage (breaks, tears, leakage, cracks, bloating etc.)
3. Missing the product information like manufacturer's name, address, Batch number, manufacturing, and expiry date stated.
4. Incorrect product information.
5. Language other than English or Kiswahili.
6. Products that have market complaints.

Samples were submitted to either the PPB or the MEDS QC laboratory for analysis using the official compendial methods, i.e., British Pharmacopoeia and United States Pharmacopoeia

Analysis request forms were filled for each of the samples submitted for compendial analysis by the PPB QC laboratory (Annex 6: Analysis request form). Each sample was assigned a unique laboratory reference number in the format SA2024-### and RT##### for PPB and MEDS respectively, for identification once logged into the laboratory sample database.

Samples were analyzed at the Laboratory using methods obtained from official compendia, i.e., British Pharmacopoeia (BP 2022), United States Pharmacopeia (USP NF 2023), International Pharmacopoeia (11th Edition) and International Standards Organization (ISO). The sampled molecules and accompanying compendial tests carried out are as shown in Table 2.5.

Table 6 Test parameters conducted

#	**Molecule**	**Test parameters**	**Laboratory**
1.	Amoxicillin Dispersible	ID, Uniformity of weight, Assay, Dissolution	PPB_QC
2.	Metronidazole	ID, Assay, pH	PPB_QC
3.	Vitamin K	ID, Assay, pH	PPB_QC
4.	Tetracycline	ID, Assay, pH	PPB_QC
5.	Iron/Folic	ID, Uniformity of dosage units, Dissolution	MEDS
6.	ORS	Uniformity of Weight, Assay	MEDS

#	Molecule	Test parameters	Laboratory
7.	Zinc sulphate	ID, Disintegration, Uniformity of dosage units	MEDS
8.	Gentamicin Injection	ID, Assay, pH	MEDS
9.	Dexamethasone Injection	ID, Assay, pH	MEDS
10.	Oxytocin Injection	ID, Assay, pH Related Substances	MEDS

2.13.1.5 Tests Requested

Combinations of the following tests were requested, depending on the drug sample formulation.

1. Consistency of formulated preparations
2. Acidity/Alkalinity
3. Dissolution
4. Identification
5. Related substances
6. Disintegration
7. Assay

2.13.1.6 Compendia used

Official and non-official compendia used in the analysis of the samples are as follows;

A. British Pharmacopoeia (BP)
B. United States Pharmacopeia National Formulary
C. Adopted Manufacturer's Method
D. International Pharmacopeia

2.13.1.7 Reagents and Solvents

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

2.13.1.8 Chemical Reference Standards

Primary chemical reference substances or working chemical reference substances traceable to a primary chemical reference substance were used in the quantitative tests.

2.13.1.9 Instrumentation

All testing equipment used were qualified and deemed appropriate for the testing required using internal standard operating procedures.

2.13.1.10 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.

2.13.2 Analytical tests

2.13.2.1 Consistency of Formulated Preparations

All the units in a pharmaceutical preparation must be consistently formulated to ensure a uniform pharmaceutical effect when the preparation is administered over a course of time across different patient populations. The Uniformity of Weight (Mass) test from the BP was used. All the HPTs samples formulated as solid dosage forms were subjected to this test.

The test involved individually weighing 20 units taken at random or, for single-dose preparations in individual containers, the contents of 20 containers. The average weight was then determined. The number of individual weights deviating from the average was then determined and evaluated against the specifications.

2.13.2.2 Acidity/Alkalinity

This is a measure of the acidity or basicity of the sample. This test was performed for all the samples in liquid dosage form. The test involved taking an appropriate volume of sample and reading its pH using a suitably

calibrated electronic pH meter. The observed value was compared against the limits specified in the appropriate monograph.

2.13.2.3 Dissolution

The dissolution test was carried out as a means of determining the *in vitro* release of active ingredients in tablet formulations into a specified volume of liquid medium maintained at 37 ± 2°C over a specified duration under carefully regulated conditions of ionic concentration, pH and agitation as specified in the appropriate monograph.

Six tablets were run individually in the dissolution tester and the amount dissolved as a percentage of the stated amount was determined using an appropriate quantification procedure as specified in the appropriate monograph.

2.13.2.4 Identification

Identification Test is a qualitative analysis performed to confirm the identity of a drug substance or excipient in a sample. It ensures that the right material has been used in the formulation or manufacturing process. The test is designed to verify the presence of a specific compound (API or excipient) by using chemical, physical or instrumental methods like HPLC, UV, IR.

Identification tests were carried out on collected samples using the relevant procedure as specified in the appropriate monograph.

2.13.2.5 Related substances

Related Substances refer to impurities that are chemically related to the API or arise during manufacturing, storage, or degradation. These substances may affect the safety, efficacy, or stability of the drug product, so their control is critical. Related substances are monitored using analytical methods like chromatography, spectroscopy as per official Pharmacopoeias or manufacturer's methods.

The collected samples were tested for related substances using the relevant procedure as specified in the appropriate monograph.

2.13.2.6 Disintegration

Disintegration Test is a quality control test used primarily in the pharmaceutical industry to determine how quickly a tablet or capsule breaks down into smaller particles when placed in a liquid medium under specific conditions. A disintegration test measures the time required for a tablet, capsule, or other solid dosage form to break apart into granules or particles under standardized conditions, usually in a simulated digestive environment (like gastric fluid at 37°C), water or buffer solution.

A disintegration tester was employed during the test and temperature was maintained mainly at 37 ± 2°C (body temperature). All the HPTs samples formulated as solid dosage forms were subjected to this test.

2.13.2.7 Assay

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.

2.13.3 Reporting of test results and out-of-specification procedures

A Certificate of Analysis (CoA) incorporating a summary of the actual method used to test each sample and the results obtained was issued for each of the 94 samples analyzed. Each CoA was given a unique certificate of analysis number in the format SA2024-### and RT##### for PPB and MEDS respectively.

A sample was considered to have passed when it complied with all tests, to fail when it did not comply with at least one (1) of the tests, and as doubtful when there were conflicting or inconclusive results for at least one (1) test.

In cases of OOS and where product analysis had adopted in-house methods and specifications, then the QC laboratory carried out re-testing of the sample using validated manufacturers/adopted in-house methods of analysis.

A Certificate of Analysis (CoA) that incorporated a summary of the actual method used to test each sample and the results obtained was issued for each sample analyzed. In addition to the CoA, an analysis report was compiled and provided by the QC laboratory.

2.14 Registration status of the sampled MNCH product

The registration status of all MNCH collected samples were verified using the PPB database. The proportion of unregistered products was determined before testing. Only registered products underwent both minilab and compendial analysis where applicable.

2.15 Data Quality Assurance, Analysis and Interpretation

2.15.1 Data Quality Assurance

The quality of data was assured through the development of a protocol for the activity and provision of standardized training to the samples and data collectors and applying standardized tools for data and samples collection. The teams carrying out data and sample collection were supervised by a central coordination team.

2.15.2 Data Analysis and Interpretation

The results of the analysis of samples were classified as either “complies or does not comply” with the specifications of the test parameters analyzed. Samples that did not comply were further disaggregated as unregistered, substandard, or falsified. The WHO’s definition was used to classify the HPTs as “Substandard or falsified”, while the PPB policy on registration of HPTs was applied in the determination of registration status of the HPTs.

2.15.3 Management of the PMS Activity

The responsibilities of the various stakeholders in this PMS Activity were as shown in Table 7.

Table 7 Responsibility Matrix

S/N	Activity	Responsibility
1.	Development of protocol for PMS of selected medicines	PV/PMS TWG, PPB, MoH, Counties, MEDS, NQCL, USP
2.	Nomination of samples and data collectors	PPB
3.	Coordination of training of sample and data collectors	PPB
4.	Coordination of training on MiniLabs	PPB and NQCL
5.	Coordination of sample and data collection- field activity	PPB
6.	Coordination of MiniLab activity	PPB
7.	Compendial testing	PPB_QCL and MEDS_QCL
8.	Laboratory report writing	PPB_QCL and MEDS_QCL
9.	Final PMS report writing	PV/PMS TWG, PPB, MoH, Counties, MEDS, NQCL
10.	Implementation of regulatory actions	PPB
11.	Dissemination of findings	PPB, PV/PMS TWG

No.	Product Name	API	Manufacturer	Results	Regulatory Action
1.	Alkem Metro	Metronidazole	R.K Laboratories (P) Ltd	Not registered	Recalled from the market
2.	Amoxicillin Comprimes Dispersible A 250mg (Dt)	Amoxicillin Trihydrate BP 250mg (DT)	Medreich Ltd	Not registered	Recalled from the market
3.	Dexamethasone	Dexamethasone Injection	Ciron Drugs & Pharmaceuticals Pvt Ltd	Not registered	Recalled from the market
8.	Oxycop	Oxytocin	Macin Remedies India Ltd	Not registered	Recalled from the market
9.	Tetracycline Hydrochloride Ophthalmic Ointment Usp	Tetracycline Hydrochloride Ointment	Systochem Laboratories Limited	Not registered	Recalled from the market
10.	Unyzone	Dexamethasone Injection	Shandong Xier Kangtai Pharmaceutical Co., Ltd	Not registered	Recalled from the market
11.	Zincopower Dt	Zinc Sulphate	Hof Pharmaceuticals Ltd	Not registered	Recalled from the market
11.	Topfoliferum Tablets	Ferrous Sulphate & Folic Acid	Liaoning Huarui Union Pharmaceutical Co., Ltd, China	Failed test on Assay	Recalled from the market
12.	Oxytocin		Laborate Pharmaceuticals India Ltd	Failed test on related substances	Recalled from the market

3. RESULTS

3.1 Samples collected

A total of two hundred and thirteen samples were collected from one hundred and thirty-six facilities across thirty-seven counties as illustrated in map figure 2. Three (3) of the facilities were Faith-based organizations, eighty-seven were private facilities and forty-six were public health facilities. Collected samples distribution is summarized in the Figure 1

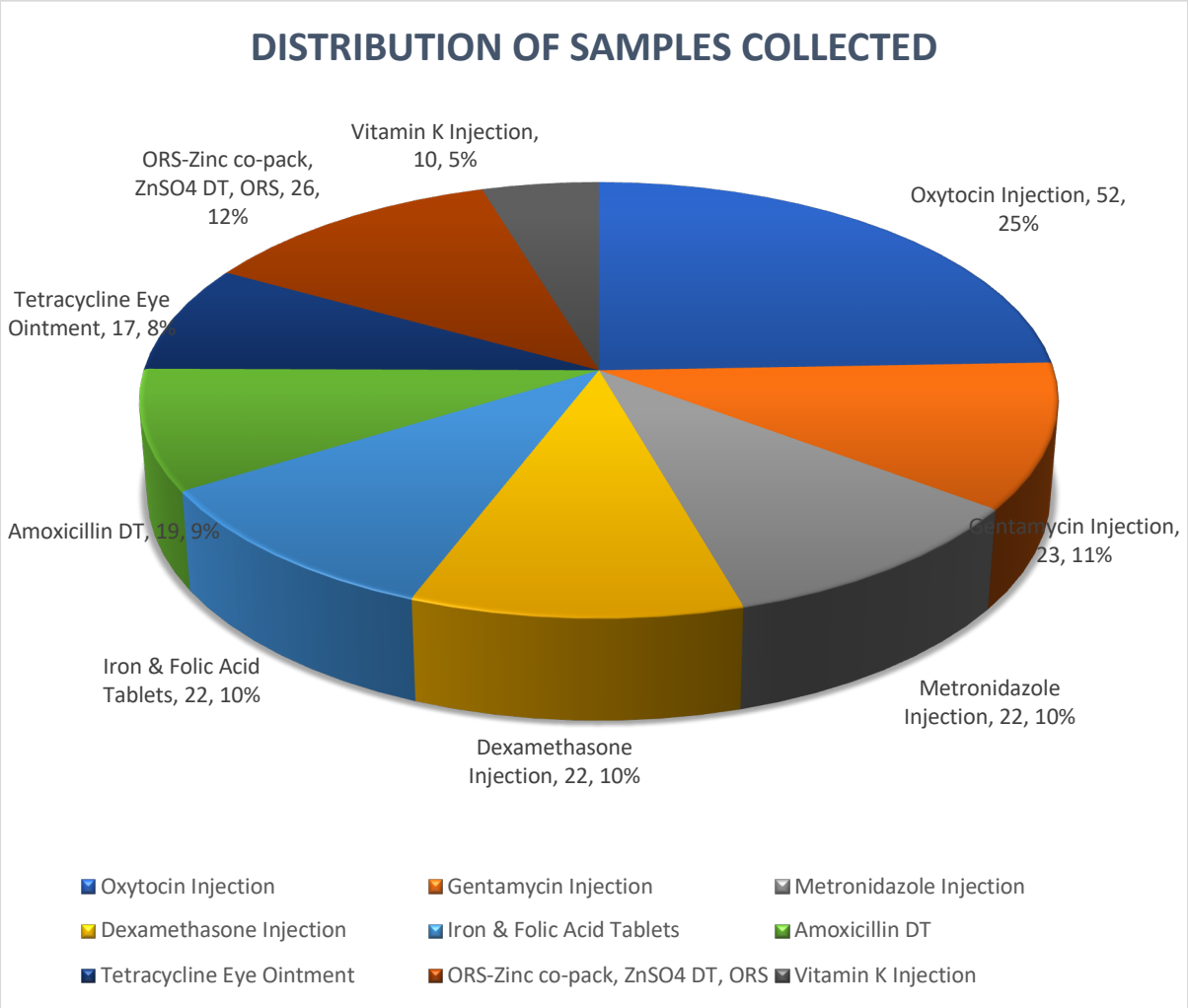

Figure 1 Distribution of samples collected

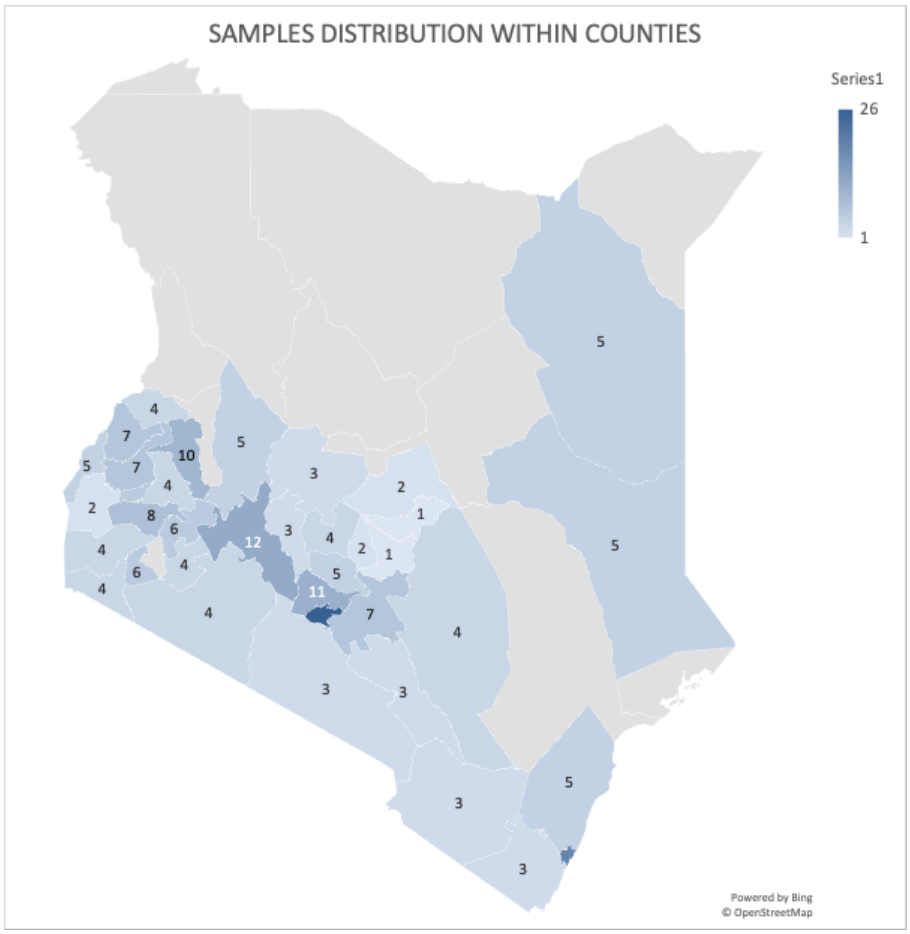

Figure 2 Samples distribution within counties

3.2 Storage conditions

Temperature and humidity monitoring was conducted within some facilities. 75 facilities were monitoring temperature while 42 facilities were monitoring humidity. 61 facilities and 94 facilities were not monitoring temperature and humidity respectively.

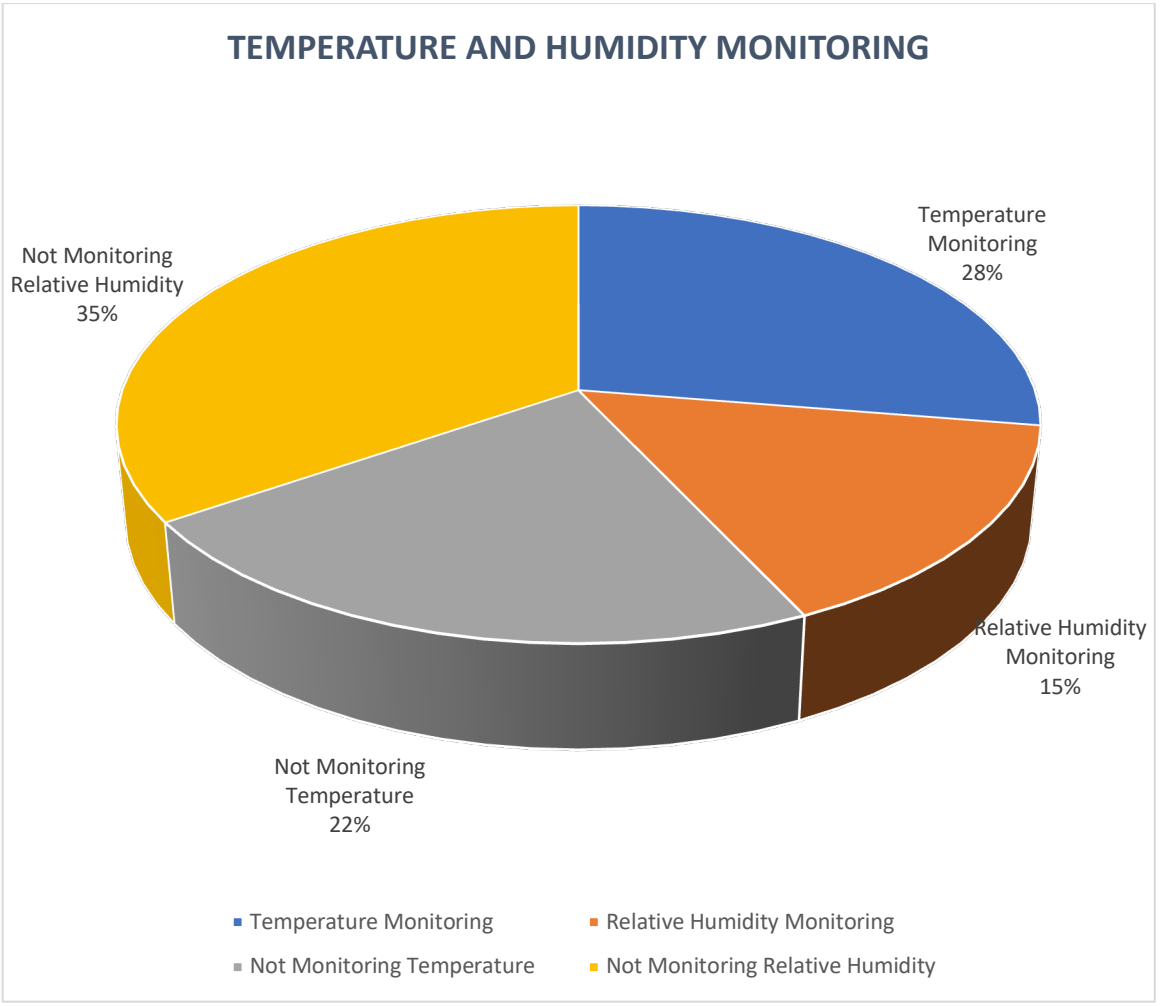

Figure 3 Temperature and Humidity Monitoring

3.2.1 Oxytocin Storage Conditions

Oxytocin injection was sampled from 32 facilities of which 26 facilities were monitoring fridge temperature while six (6) facilities were not monitoring fridge temperature. Six (6) facilities had temperatures above or below 2°C-8°C with 33°C being the highest and -0.2°C being the lowest.

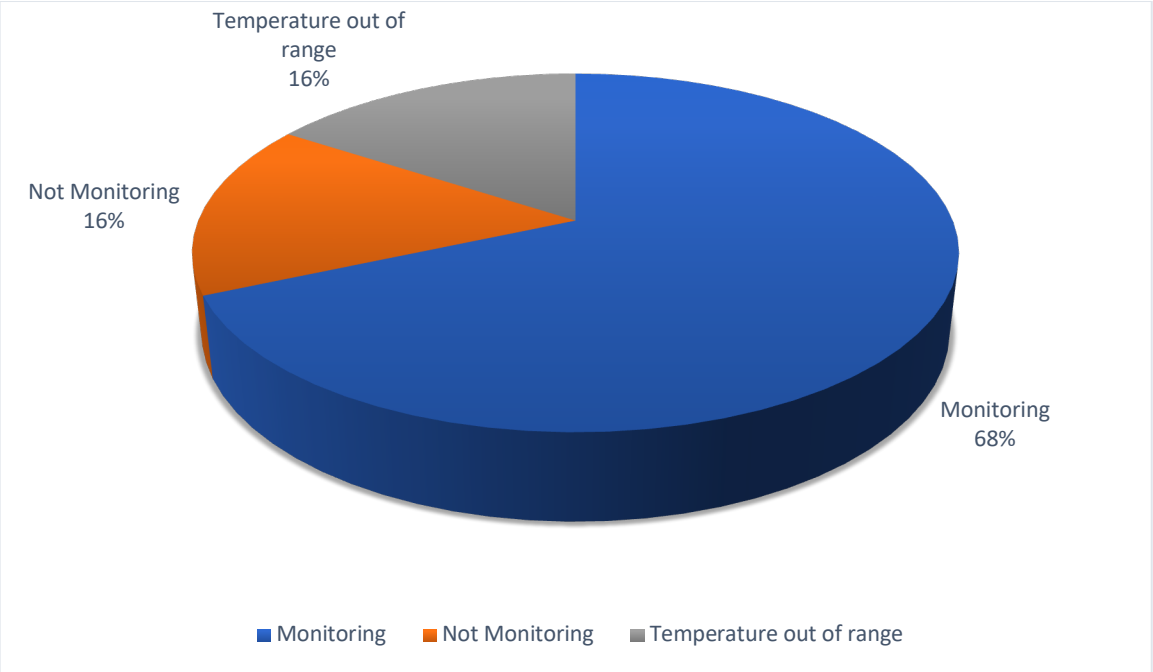

Figure 4 Fridge Temperature Monitoring

3.3 Registration status

A total of 51 unique brands out of the 58 collected during the PMS were confirmed as registered while seven products brands were found to be unregistered. See Figure 5.

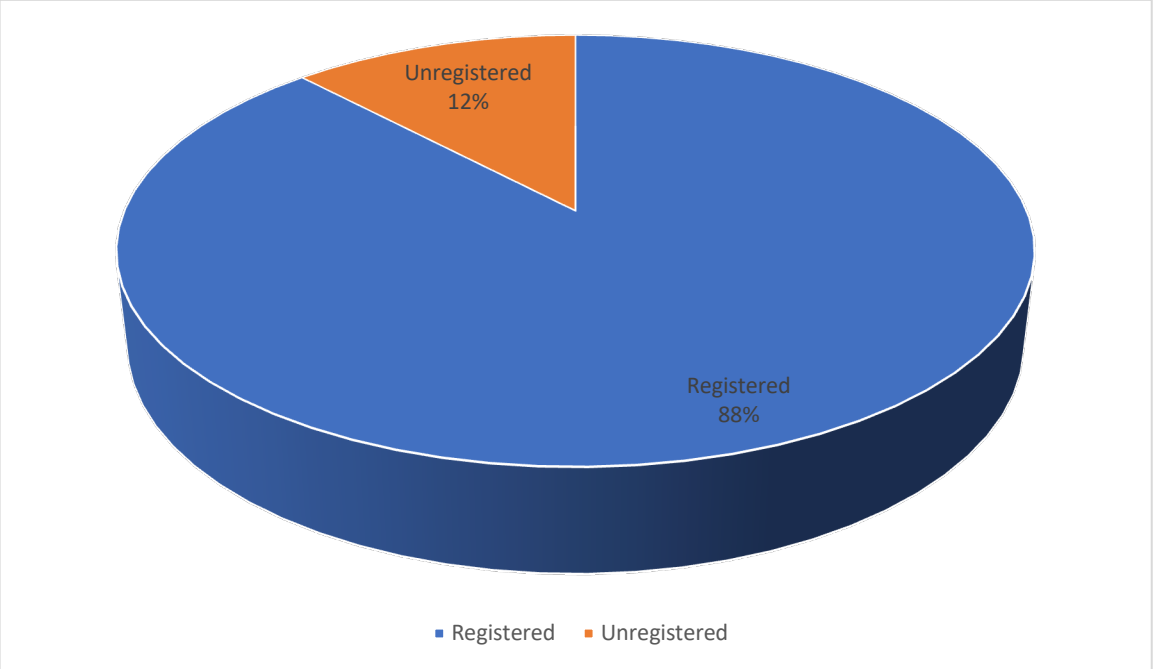

Figure 5 Registration status

3.4 Physical/Visual Screening

All the two hundred and thirteen samples were subjected to physical/visual screening. One (1) sample Kemoxyl DT (Amoxicillin Trihydrate) batch no. 85439 failed physical/visual screening whereby presence of yellow spots on the surface and inside the tablets was evident.

3.5 Field screening using Minilab technique

A total of eighty-five samples were subjected to screening using minilab technique. These included Amoxicillin 250mg DT eighteen, Dexamethasone Injection twenty-two, Metronidazole Injection twenty-two and Gentamycin Injection twenty-three as illustrated in the Figure 6. The oral solid dosage forms (Amoxicillin 250mg DT) were also subjected to disintegration tests.

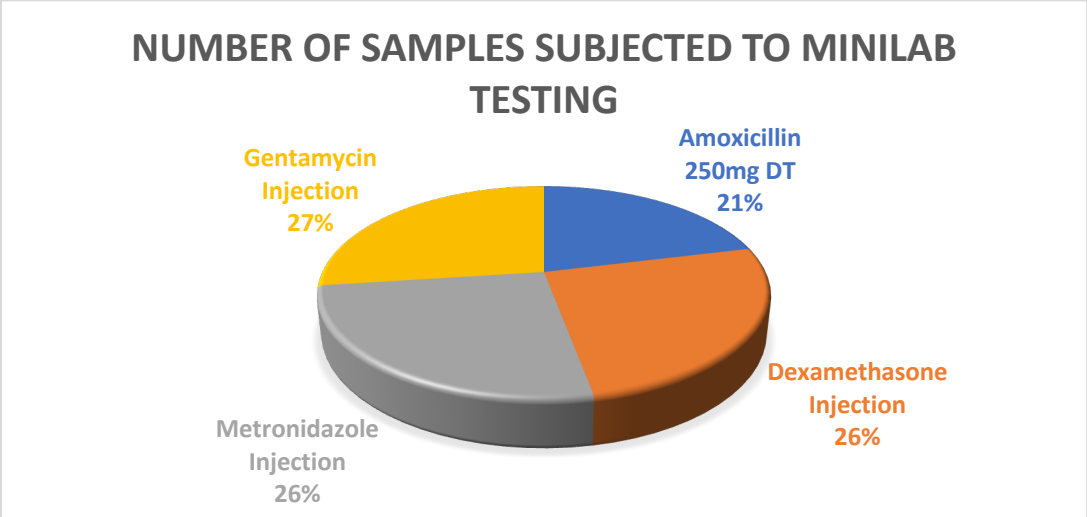

Figure 6 Samples subjected to MiniLab

All the samples passed the minilab screening tests.

3.6 Confirmatory Testing

For compendial testing, ninety four (94) samples were analyzed.

Table 8 List of molecules Tested

Molecule name	No of Samples	Complied	Does not comply	Inconclusive	Number of brands
Metronidazole	7	7	-	-	5
Vitamin K	8	8	-	-	2
Dexamethasone	4	4	-	-	3
TEO	12	8	-	4	6

Molecule name	No of Samples	Complied	Does not comply	Inconclusive	Number of brands
Amoxicillin	4	4	-	-	3
Gentamycin	5	5	-		4
Iron & Folic acid	17	14	3	0	4
Oxytocin	23	22	1	-	4
ORS	4	4	-	-	3
ORS + Zinc	9	9	-	-	5
Zinc Tablets	1	1	-	-	1
Total	94	85	4	4	40

3.6.1 Dexamethasone Sodium Phosphate Injection

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC	USP 43 NF 38	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution as obtained in the Assay.
Extractable Volume	USP 43 NF 38	The Volume is not less than the sum of the nominal volume of the containers taken collectively (n=10)
pH	USP 43 NF 38	7.0 – 8.5
Assay by HPLC	USP 43 NF 38	90.0% to 115.0% of the stated amount

The four (4) samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as shown in Table 3.3.

Table 9 Dexamethasone Sodium Phosphate Injection Sample Details and Analysis Results

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Extractable Volume	pH	Assay
		County	Facility							
1.	KJD/DEX/20.09.2024/012	Kajiado	Kajiado County Referral Hospital	Dexamedron	Geofman pharmaceuticals	2305	Complies	10 mL	7.9	112.9
2.	NYR/DEX/20.09.2024/014	Nyeri	Outspan Hospital Nyeri	Dexamethasone	Tianjin King York Group Hubei, Tian Yao Pharmaceutical Co. Ltd	2406011	Complies	10 mL	8.0	101.6%

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Extractable Volume	pH	Assay
		County	Facility							
3.	KSI/AMX/22.09.2024/022	Kisii	Sakapharm	Dexamethasone	Tianjin King York Group Hubei, Tian Yao Pharmaceutical Co. Ltd	2312291	Complies	10 mL	8.0	101.5%
4.	KKA/DEX/19.09.2024/008	Kakamega	Kakamega County Referral Hospital	Dexalab	Laborate Pharmaceuticals India Ltd	NXDIE-009	Complies	10 mL	7.4	94.5%

3.6.2 Gentamicin Sulphate Injection Samples

The following tests were carried out:

Test	Compendia	Specifications
Identification by TLC	BP 2021	The three principal spots in the chromatogram obtained with solution (1) corresponds to the chromatogram obtained with solution (2)
Identification by HPLC	BP 2021	The retention times of the four peaks in the chromatogram obtained with solution 2 correspond to those of the four principal peaks in the chromatogram obtained with solution 1
Extractable Volume	BP 2021	The Volume is not less than the sum of the nominal volume of the containers taken collectively (n=10)
pH	BP 2021	3.0 – 5.5
Gentamicin Sulfate Composition by HPLC	BP 2021	C1: 25.0 to 50.0% C1a: 10.0 to 35.0% C2 + C2a: 25.0 to 55.0%
Microbiological Assay	BP 2021	Lower fiducial limits: Not More Than 110% Upper fiducial limits: Not Less Than 97%

The five (5) Gentamicin Sulpate Injection samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 3.4.

Table 10 Gentamicin Sulphate Injection Sample Details and Analysis Results

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Extractable Volume	pH	Assay
		County	Facility							
1.	KTU/GNT/23.09.2023/012	Kitui	Nunguni chemist limited	Genycin	Shandong Xier Kangtai Pharmaceutical Co. Ltd	231263	Complies	20 mL	4.9	Lower: 99.7% Upper: 107.7%
2.	VHG/GNT/18.09.2024/006	Vihiga	Vihiga Drug Mart	Gentaplus-80	Tianjin KingYork Group Hubei TianYao Co., Ltd	231201	Complies	20 mL	5.1	Lower: 100.0% Upper: 107.8%
3.	NBI/GNT/21.09.2024/022	Nairobi	Salama pharmaceuticals ltd - Moi Avenue	Gentamycin sulphate Injection	Reyoung pharmaceutical co. Ltd	202307114	Complies	20 mL	4.9	Lower: 106.9% Upper: 114.9%
4.	TNZ/GNT/21.09.2024/020	Trans Nzoia	Kiminini Cottage Mission Hospital	Gentobit-40	Vital Health Pvt Ltd	V23108	Complies	20 mL	4.9	Lower: 96.5% Upper: 102.9%
5.	KWL/GMT/P/19.09.2024/017	Kwale	Jorrychem Pharmacy	Gentaplus-80	Tianjin KingYork Group Hubei Tianyao Pharmaceutical Co. Ltd	231049	Complies	20 mL	5.2	Lower: 106.2% Upper: 109.2%

3.6.3 Metronidazole Intravenous Infusion Samples

The following tests were carried out:

Test	Compendia	Specifications
Identification	USP NF 2024	The retention times of the major peak of the sample solution corresponds to that of the standard solution, as obtained in the Assay
Assay	USP NF 2024	Contains not less than 90.0% and not more than 110.0% of the stated amount of Metronidazole

All the seven samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 3.5.

Table 11 Metronidazole Intravenous Infusion Sample Details and Analysis Results

	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	Identification	Assay
		County	Facility					
1	NKR/MTZ/22.09.2024/019	Nakuru	Transmega (K) Ltd	Metrogen	Aveo Pharmaceuticals Pvt Ltd	HF242385	Complies	102.90%
2	TVT/MTZ/23.09.2024/028	Taita Taveta	Dawida Maternity and Nursing Home	Abagyl Intravenous Infusion	Abacus Parenteral Drugs Ltd	26H00124	Complies	97.11%
3	KKA/MTZ/19.09.2024/007	Kakamega	Kakamega County Referral Hospital	Abagyl Intravenous Infusion	Abacus Parenteral Drugs Ltd	26E02524	Complies	100.08%
4	GRS/MTZ/24.09.2024/019	Garissa	Kendia Pharmaceutical	Metroglax	Aishwarya Healthcare	A3292E	Complies	96.98%
5	NBI/MTZ/20.09.2024/015	Nairobi	Range chem pharmaceuticals	Unique's Metrogyl	Unique Pharmaceutical Laboratories	PIX24190	Complies	93.69%
6	NRK/MTZ/18.09.2024/004	Narok	Baraka Hospital	Medzol	Tianjin King York Group	231290	Complies	97.26%
7	LKP/MTZ/24.09.2024/025	Laikipia	Pharma and Allied Ltd	Axagyl	Axa Parenterals Ltd	D130278	Complies	98.59%

3.6.4 Oxytocin Injection

The following tests were carried out:

Test	**Compendia**	**Specifications**
Identification by HPLC	BP 2024	In the Assay, the chromatogram obtained with solution (1) exhibits a peak with the same retention time as the principal peak in the chromatogram obtained with solution (2)
Extractable Volume	BP 2024	**n=5** The volume is not less than the sum of the nominal volume of the containers taken collectively
Related Substances	BP 2024	**Any secondary peaks:** In the chromatogram obtained with solution 1, the area of any secondary peak is not greater than 0.7 times the area of the principal peak in the chromagram obtained with solution 2 (1.5%) **Sum of the Areas of any Secondary Peaks:** In the chromatogram obtained with solution 1, the sum of the areas of any secondary peaks is not greater than 2.5 times the principal peak in the chromatogram obtained with solution 2 (5%)
Acidity	BP 2024	3.5 to 4.5
Assay by HPLC	BP 2024	90.0% to 110.0% of the stated amount

Twenty-two (22) samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia. One (1) sample, KRG/OXY/P/19.09.2024/009, did not comply with the test for the Related Substances as shown in Table 3.6.

Table 12 Oxytocin Sample Details and Analysis Results

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Extr. Volume	RS	pH	Assay
		County	Facility								
1.	NBI/OXY/P/20.09.2024/016	Nairobi	The Reliance hospital	Syntocinon	M/S Sovereign Pharma Pvt Limited	SM0321002	Complies	5.0ml	0.9%, 0.9%	3.7	97.5 %
2.	NYR/OXY/M/19.09.2024/007	Nyeri	Karatina sub-county hospital	Syntocinon	M/S Sovereign Pharama Private Ltd	SM0321002	Complies	5.0ml	0.7%, 0.7%	3.7	97.4 %
3.	NKR/OXY/P/20.09.2024/020	Nakuru	Our Lady of Mercy Mission Hospital	Syntocinon	M/S Sovereign Pharama Private Ltd	SM0321002	Complies	5.0ml	0.8%, 0.8%	3.7	95.7 %
8.	KRG/OXY/M/19.09.2024/008	Kirinyaga	Kerugoya county referral hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3026	Complies	5.0ml	0.0%, 0.0%	4.0	97.8 %
9.	EMB/OXY/P/20.09.2024/010	Embu	Embu level 5 hoapital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3023	Complies	5.0ml	0.0%, 0.0%	3.7	95.8 %
10.	BMT/OXY/M/18.09.2024/006	Bomet	Longisa Referral Hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3029	Complies	5.0ml	0.0%, 0.0%	4.1	98.8 %
11.	VHG/OXYM/18.09.2024/004	Vihiga	Vihiga County Referral Hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3025	Complies	5.0ml	0.43%, 0.79%	3.8	96.0 %
12.	KMB/OXY/M/18.09.2024/007	Kiambu	Igegania Sub-county hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY4002	Complies	5.0ml	0.5%, 0.5%	4.2	98.9 %
13.	NYR/OXY/P/19.09.2024/006	Nyeri	Karatina sub-county hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3029	Complies	5.0ml	0.0%, 0.0%	4.1	97.4 %
14.	MSA/OXY/M/18.09.2024/007	Mombasa	Port Reitz Sub-County Hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3022	Complies	5.0ml	0.0%, 0.0%	4.1	97.1 %
15.	KMB/OXY/M/18.09.2024/006	Kiambu	Igegania Sub-County Hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3006	Complies	5.0ml	0.8%, 0.8%	3.8	94.8 %
16.	KRG/OXY/P/19.09.2024/009	Kirinyaga	Kerugoya County Referral Hospital	Oxytocin	Laborate Pharmaceuticals India Ltd	MOEIE-003	Complies	5.0ml	7.6%, 11.9%	4.0	104.2%
17.	MRG/OXY/P/18.09.2024/004	Murang'a	Muranga County Referral Hospital	Oxytocin	Laborate Pharmaceuticals India Ltd	NOEIE-008	Complies	5.0ml	0.7%, 1.3%	4.0	93.0 %
18.	MRG/OXY/M/18.09.2024/005	Murang'a	Muranga County Referral Hospital	Oxytocin	Laborate Pharmaceuticals India Ltd	NOEIE-009	Complies	5.0ml	0.5%, 0.5%	4.0	95.0 %

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Extr. Volume	RS	pH	Assay
		County	Facility								
19.	KRC/OXY/P/19.09.2024/013	Kericho	Kipkelion Sub County Hospital	Curtocin	Makcur Laboratories Ltd	ML24302	Complies	5.0ml	0.7%, 0.7%	4.0	104.2%
20.	KRC/OXY/M/19.09.2024/014	Kericho	Kipkelion Sub County Hospital	Curtocin	Makcur Laboratories Ltd	ML24302	Complies	5.0ml	0.0%, 0.0%	4.2	104.2%
21.	BMT/OXY/P/18.09.2024/005	Bomet	Longisa Referral Hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3029	Complies	5.0ml	0.0%, 0.0%	3.8	97.1%
22.	TVT/OXY/P/23.09.2024/029	Taveta	Mwatate Sub County Hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3029	Complies	5.0ml	0.7%, 0.7%	4.1	97.1%
23.	BSA/OXY/P/19.09.2024/017	Busia	New Busia Maternity and Nursing Home	Curtocin	Makcur Laboratories Ltd	ML24302	Complies	5.0ml	0.2%, 0.6%	4.2	108.2%
24.	BRG/OXY/P/20.09.2024/015	Baringo	Eldama Ravine Sub-County Referral Hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3027	Complies	5.0ml	0.3%, 0.7%	4.2	98.3%
25.	UGS/OXY/M/19.09.2024/010	Uasin Gishu	Moi Teaching and Referral Hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3026	Complies	5.0ml	0.4%, 0.7%	4.2	100.5%
26.	KKA/OXY/P/19.09.2024/010	Kakamega	Makunga Sub-County Hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY4001	Complies	5.0ml	0.4%, 1.1%	4.2	100.9%
27.	UGS/OXY/19.09.2024/009	Uasin Gishu	Moi Teaching and Referral Hospital	Oxyt	Kilitch Drugs (India) Ltd	KLOY3026	Complies	5.0ml	0.5%, 1.6%	4.1	98.0%

3.6.5 Phytomenadione Injection

The following tests were carried out:

Test	Compendia	Specifications
Identification A. by UV	BP 2024	The light absorption of the solution, in the range 230 to 350nm exhibits a maximum at 328nm and a minimum at 292nm.
Identification B. by UV	BP 2024	The light absorption of the solution, Appendix IIB, in the range 230 to 350nm exhibits maxima at 245, 249, 263 and 271nm and minima at 256nm.
Extractable Volume	BP 2024	The volume is not less than the sum of the nominal volume of the containers taken collectively. (n=5)

Test	Compendia	Specifications
pH	BP 2024	5.0 to 7.5
Assay by HPLC	BP 2024	90.0% to 115.0% of the stated amount.

All the eight (8) samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 3.7.

Table 13 Phytomenadione Injection 10%v/v Samples Details and Analysis Results

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Extr. Volume	pH	Assay
		County	Facility							
1.	WJR/VITK/26.09.2024/025	Wajir	Medina Pharmacy Ltd. - Wajir	Phytoz	Makcur Laboratories Limited	ML23668	Complies	1.0ml	6.0	101.8%
2.	MSA/VTK/P/20.09.2024/024	Mombasa	Mombasa Hospital	Konakion MM Paediatric	Cenexi SAS 52 Rue Marcel ET Jacques Gaucher	F3123F03	Complies	1.0ml	5.9	101.7%
3.	NBI/VTK/20.09.2024/019	Nairobi	The Reliance hospital	Konakion MM Paediatric	Cenexi SAS 52 Rue Marcel ET Jacques Gaucher	F3123F03	Complies	1.0ml	5.9	101.5%
4.	VHG/VTK/18.09.2024/003	Vihiga	Bahiga Town Centre Chemist	Inj. K MM Pediatric	Incepta Pharmaceuticals Ltd	24010	Complies	1.0ml	5.9	101.6%
5.	NKR/VTK/21.09.2024/017	Nakuru	Supreme Pharmacy Ltd	Inj. K MM Pediatric	Incepta Pharmaceuticals Ltd	23030	Complies	1.0ml	5.9	101.6%
6.	KSM/VTK/19.09.2024/006	Kisumu	Victoria Healtcare Limited	Inj. K MM Pediatric	Incepta Pharmaceuticals Ltd	23030	Complies	1.0ml	5.9	101.6%
7.	KKA/VTK/19.09.2024/009	Kakamega	Kakamega County Referral Hospital	Inj. K MM Pediatric	Incepta Pharmaceuticals Ltd	24010	Complies	1.0ml	5.9	101.6%
8.	KSM/VTK/20.09.2024/008	Kisumu	Africa Inuka Hospital	Inj. K MM Pediatric	Incepta Pharmaceuticals Ltd	24010	Complies	1.0ml	5.9	101.5%

3.6.6 Dried Ferrous Sulphate 200 mg plus Folic Acid 400 mcg tablets

The following tests were carried out:

Test	Compendia	Specifications
Identification by Chemical Reaction (Sulfate)	In-House	A white precipitate is formed.
Identification By HPLC	In-House	The Retention times of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay.
Disintegration Time (DT)	In-House	All six tablets disintegrate within 30 minutes in water.
Mass Uniformity	In-House	Not more than two tablets deviate by 5.0% and none by 10.0% from the average weight.
Assay By Titration	In-House	**Ferrous Sulfate:** 80.0% to 90.0% of the stated amount.
Assay By HPLC	In-House	**Folic acid:** 90.0% to 140.0% of the stated amount.

Twelve (12) samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia. Three (3) samples failed to meet the testing are currently undergoing OOS investigation and pending release of CoA as illustrated in Table 3.8.

Table 14 Dried Ferrous Sulphate 200 mg plus Folic Acid 400 mcg tablets Sample Details and Analysis Results

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	DT	UoW	Assay
		County	Facility							
1.	BRG/FEF/20.09.2024/016	Baringo	Eldacare Pharmacy	Topfoliferum	Liaoning Huarui Union Pharma Co. LTD	240105	Complies		Complies	**Ferrous Sulfate:** 55.1% **Folic Acid:** 20.0%
2.	KMB/FEF/19.09.2024/008	Kiambu	Pharma and Allied Logistics	IFAS	Treffer pharmaceuticals	26014	Complies	Complies	Complies	**Ferrous Sulfate:** 88.5% **Folic Acid:** 110.2%
3.	NYR/FEF/20.09.2024/013	Nyeri	Livingcare medical	Ferrolic- LF	Laboratory & Allied Ltd.	85037	Complies	Complies	Complies	**Ferrous Sulfate:** 88.3% **Folic Acid:** 94.9%

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	DT	UoW	Assay
		County	Facility							
4.	TNT/FEF/20.09.2024/011	Tharaka Nithi	Nyagani dispensary	Ferrolic- LF	Laboratory & Allied Ltd.	82226	Complies	Complies	Complies	**Ferrous Sulfate:** 81.7% **Folic Acid:** 92.6%
5.	BGM/FEF/20.09.2024/022	Bungoma	Calvary Hope Medical Centre	Topfoliferum	Liaoning Huarui Union Pharma Co. LTD	240415	Complies	Complies	Complies	**Ferrous Sulfate:** 82.6% **Folic Acid:** 23.8%
6.	NBI/FEF/21.09.2024/023	Nairobi	Salama pharmaceuticals ltd - Moi Avenue	Sofron	Treffer pharmaceuticals	15508	Complies	Complies	Complies	**Ferrous Sulfate:** 88.5% **Folic Acid:** 96.4%
7.	MRU/FEF/20.09.2024/012	Meru	St. Rita hospital	Ferrolic- LF	Laboratory & Allied Ltd.	86134	Complies	Complies	Complies	**Ferrous Sulfate:** 89.0% **Folic Acid:** 106.5%
8.	KLF/FEF/20.09.2024/021	Kilifi	St Lukes ACK Mission Nursing Home	Topfoliferum	Liaoning Huarui Union Pharma Co., Ltd	240105	Complies	Complies	Complies	**Ferrous Sulfate:** 55.3% **Folic Acid:** 20.6%
9.	MSA/FEF/18.19.2024/010	Mombasa	Antidote Pharmacy	Ferrolic- LF	Laboratory & Allied Ltd	86255	Complies	Complies	Complies	**Ferrous Sulfate:** 89.0% **Folic Acid:** 102.2%
10.	MCK/FEF/23.09.2024/011	Machakos	Debbipharm pharmaceuticals	Ferrolic- LF	Laboratory & Allied Ltd.	86256	Complies	Complies	Complies	**Ferrous Sulfate:** 86.9% **Folic Acid:** 110.2%
11.	GRS/FEF/24.09.2024/016	Garissa	Garissa Level 5 Teaching and Referral Hospital	Ferrolic- LF	Laboratory & Allied Ltd.	85039	Complies	Complies	Complies	**Ferrous Sulfate:** 88.4% **Folic Acid:** 99.3%
12.	KSI/FEF/22.09.2024/024	Kisii	WALM Chemist	Ferrolic- LF	Laboratory & Allied Ltd.	86255	Complies	Complies	Complies	**Ferrous Sulfate:** 89.0% **Folic Acid:** 106.2%
13.	LKP/FEF/24.09.2024/024	Laikipia	Kapepharm Pharmacy	Ferrolic- LF	Laboratory & Allied Ltd.	86134	Complies	Complies	Complies	**Ferrous Sulfate:** 89.0% **Folic Acid:** 105.5%
14.	NDI/FEF/19.09.2024/013	Nandi	Kapsabet County Referral Hospital	Ferrolic- LF	Laboratory & Allied Ltd.	84899	Complies	Complies	Complies	**Ferrous Sulfate:** 88.0% **Folic Acid:** 103.5%

3.6.7 Glucose Anhydrous; Potassium Chloride; tri-Sodium Citrate; Sodium Chloride; Zinc tablets (co-pack)

The following tests were carried out:

Test	Compendia	Specifications
Identification A. By Chemical Test (ORS)	BP 2024	When heated with Cupri-tartaric solution R1 a copious precipitate of Copper (I) Oxide is produced.
Identification B. for Potassium salts By Chemical Test (ORS)	BP 2024	**Test for Potassium and Potassium salts** TESTB: A yellow or orange-yellow precipitate is formed when 40 mg of the Sample to be examined in 1ml water is added. 1ml of dilute acetic acid and 1ml of freshly prepared 100g/L of sodium cobalt Nitrite.
Identification C. By Chemical Test (ORS)	BP 2024	**Test for Sodium and Sodium salts** TEST A : No precipitate is formed when 2 ml of a 150g/ solution of Potassium Carbonate R is added A dense white precipitate is formed when 4mls Potassium Pyroantimonate Solution R is added heated to boiling and allowed to cool in iced water.
Identification D. By Chemical Test (Chlorides)	BP 2024	TEST :A A curdled white precipitate is formed when 2ml of the test solution is dissolved in 2ml distilled water R, acidified with dilute Nitric Acid 2ml distilled water R, acidified with dilute Nitric R and 0.4ml of Silver Nitrate Solution R1 added and allowed to stand. The Precipitate dissolves easily with exception of a few large particles which dissolve slowly when the above precipitate is centrifuged, washed with three 1ml quantities of water R and 1.5 ml of Ammonia R
Identification E. By Chemical Test (Citrates)	BP 2024	TESTA - Addition of an excess of concentrated Ammonia R produces violet Colour. Turning to violet-blue. TEST B. No precipitate is produced when a solution of Calcium Chloride is added to a neutral sample solution . White precipitate is produced when the sample solution is boiled which is soluble in 6M Acetic acid.
Identification for Sulphate by Chemical test	BP 2024	A white precipitate is formed when 1ml of Hydrochloric Acid solution and 1ml of Barium Chloride solution are added to 5 ml of Sample solution.

Test	Compendia	Specifications
Identification A. By Chemical Test (Zinc Sulfate)	BP 2024	5ml of sample solution add0.2 ml of Sodium Hydroxide solution, a white precipitate is formed. When additional 2 ml of Sodium Hydroxide solution is added, the precipitate dissolves. When 10ml of Ammonium Chloride solution is added, the solution remains clear. When 0.1ml of Sodium Sulphide is added, a flocculent white precipitate is formed.
Identification B. By Chemical Test (Zinc Sulfate)	BP 2024	A white precipitate is formed.
Disintegration (Zinc Sulfate)	BP 2024	All the six tablets disintegrate within 15 minutes.
Mass Uniformity (ORS, ZnSO4)	BP 2024	NMT 2 tablets deviate by 5.0% and none by 10.0% from the average weight.
Weight Variation (Zinc Sulfate)	BP 2024	Maximum acceptance value for 10 units not more than 15
Assay by Titration (ORS)	BP 2024	90.0% to 110.0% of the stated amount.
Assay by Titration (ZnSO4)	BP 2024	95.0% to 105.0% of the stated amount.
Assay Elemental (ORS)	BP 2024	90.0% to 110.0% of the stated amount.

All the thirteen samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as illustrated in Table 3.9.

Table 15 ORS and ORS+ Zinc tablets (co-pack) Sample Details and Analysis Results

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	DT	Mass Uniformity/ Weight Variation	Assay
		County	Facility							
1.	MRG/ORZ/18.09.2024/003	Muranga	Ihigaini dispensary kagema sub county	Co-Pack for Diarrhoea Treatment (Unilyte-N	Universal corporation ltd	681284		≤ 3	Complies	Chlorides: 101.4% Citrates: 102.3% Glucose: 102.3% ZnSO4: 100.3%

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	DT	Mass Uniformity/ Weight Variation	Assay
		County	Facility							
				and Zeenk 20) - Zeerol			Complies			Na: 93.7% K: 101.0%
2.	WJR/ORZ/26.09.2024/023	Wajir	Wajir County Refferal Hospital	Zeerol/Zeenk 20	Universal corporation Ltd	6813686	Complies	≤ 5	Complies	Chlorides: 102.9% Citrates: 102.9% Glucose: 103.3% ZnSO4: 100.3% Na: 94.4% K: 99.3%
3.	MCK/ORS/18.09.2024/003	Machakos	Backwell Pharmacy	ORS	Laboratory & Allied Ltd.	85887	Complies	No Test (-)	Complies	Chlorides: 101.1% Citrates: 101.3% Glucose: 98.9% Na: 94.8% K: 104.2%
4.	TNZ/DTZ/23.09.2024/021	Trans Nzoia	Saboti Subcounty	Diagone-Kit	Laboratory and Allied Ltd	84234/ 84237	Complies	≤ 3	Complies	Chlorides: 108.7% Citrates: 96.8% Glucose: 101.1% ZnSO4: 100.2% Na: 99.6% K: 102.3%
5.	KWL/ORZ/19.09.2024/018	Kwale	Alwalidayn Dispensary	Electrorush	Hallewood Laboratories Pvt Ltd	SF23003	Complies	No Test (-)	Complies	Chlorides: 103.6% Citrates: 105.1% Glucose: 101.8% Na: 96.5% K: 98.7%
6.	MGR/ORS/21.09.2024/018	Migori	MOLI Pharmacy	ORS	Laboratory and Allied	83717	Complies	No Test (-)	Complies	Chlorides: 99.7% Citrates: 98.1% Glucose: 96.2% Na: 96.4% K: 94.6%
7.	VHG/ORZ/18.09.2024/002	Vihiga	Esiarambatsi Health Centre	Co-Pack for Diarrhoea Treatment (Unilyte-N and Zeenk 20) - Zeerol	Universal Corporation Ltd	6814024	Complies	≤ 3	Complies	Chlorides: 98.0% Citrates: 96.8% Glucose: 100.1% ZnSO4: 100.2% Na: 94.0% K: 100.4%

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	DT	Mass Uniformity/ Weight Variation	Assay
		County	Facility							
8.	KMB/DTZ/23.09.2024/038	Kiambu	Kiambu County referral hospital	Diagone-Kit	Laboratory and Allied Ltd	84849/84851	Complies	≤ 3	Complies	Chlorides: 108.7% Citrates: 96.8% Glucose: 101.1% ZnSO4: 100.2% Na: 99.6% K: 102.3%
9.	KSM/ORS/19.09.2024/007	Kisumu	Victoria Healtcare Limited	Electrorush	Halewood Laboratories Pvt Ltd	SF 24004	Complies	No Test (-)	Complies	Chlorides: 106.5% Citrates: 105.0% Glucose: 102.6% Na: 99.2% K: 104.4%
10	MSA/ORZ/21.09.2024/026	Mombasa	Makadara Chemists-Bamburi	DTS-Z Kit	Cosmos Limited	2303534/230345	Complies	≤ 3	Complies	Chlorides: 103.6% Citrates: 105.1% Glucose: 105.7% ZnSO4: 99.6% Na: 98.4% K: 101.9%
11	NBI/ORZ/20.09.2024/014	Nairobi	Range chem pharmaceuticals	DTS-Z Kit	Cosmos limited	230352/230345	Complies	≤ 3	Complies	Chlorides: 99.3% Citrates: 100.5% Glucose: 104.0% ZnSO4: 99.6% Na: 102.8% K: 103.7%
12	NDI/ORZ/19.09.2024/014	Nandi	Mosoriot Sub-County Hospital	DTS-Z Kit	Cosmos limited	230350/230345	Complies	≤ 3	Complies	Chlorides: 100.6% Citrates: 104.2% Glucose: 102.5% ZnSO4: 100.2% Na: 98.0% K: 97.9%
13	BGM/ORS/20.09.2024/023	Bungoma	Eyat Pharmacy	Orasol - Oral Rehydration salts	Biodeal Laboraties Ltd	1123108	Complies	No Test (-)	Complies	Chlorides: 97.1% Citrates: 92.3% Glucose: 103.1% Na: 107.5% K: 101.8%

1.1.1.1 3.4.8 Tetracycline Eye Ointment

The following tests were carried out:

Test	Compendia	Specifications
Identification By HPLC	USP NF	The retention time of the Tetracycline hydrochloride peak of the sample solution corresponds to that of the standard solution
Assay By HPLC	USP NF	90.0% to 125.0%

All the eight (8) samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as shown in Table 3.10.

Table 16 Tetracycline Eye Ointment Sample Details and Analysis Results

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Assay
		County	Facility					
1.	SYA/TEO/19.09.2024/009	Siaya	Haven Hospital	DETERACIN	Vital Healthcare Ltd	E22118	Complies	92.81%
2.	UGS/TEO/18.09.2024/007	Uasin Gishu	Medilink Plus Chemist	Tetracycline Hydrochloride Ophthalmic Ointment USP	Systochem Laboratories Limited	ST-01	Complies	90.61%
3.	MRG/TEO/18.09.2024/001	Muranga	SabaSaba Health Centre	Racycline	Laboratory & allied Ltd	60423	Complies	97.03%
4.	MCK/TEO/19.09.2024/008	Machakos	Kathiani Level 4 Hospital	Racycline	Laboratory & Allied Ltd.	70923	Complies	93.34%
5.	TVT/TEO/23.09.2-24/030	Taita Taveta	Mvoi Pharmaceuticals	Deteracin	Healthcare PVT	E23043	Complies	91.96%
6.	KMB/T.E.O/23.09.2024/039	Kiambu	Kiambu County referral hospital	Racycline	Laboratory & allied Ltd	090324	Complies	92.21%
7.	NBI/TEO/20.09.2024/018	Nairobi	The Reliance hospital	Racycline	Laboratory & allied Ltd	080324	Complies	95.16%
8.	KSI/AMX/22.09.2024/023	Kisii	SAKAPHARM	DETERACIN	Vital Healthcare Limited	E23039	Complies	101.09 %

3.6.8 Amoxicillin Trihydrate BP 250mg (DT)

The following tests were carried out:

Test	Compendia	Specifications
Identification by HPLC	USP NF	The retention time of the major peak of the sample solution corresponds to that of the standard solution
Mass/Uniformity of Weight	USP NF	NMT 2 tablets deviates from the mean by more than +/-5 % and none deviates by more +/-10%
Assay by HPLC	USP NF	90.0%-110.0%
Dissolution	USP NF	S1: NLT 80% (Q)

All the four (4) samples complied with the specifications for the aforementioned tests performed as per the requirements of the appropriate compendia as shown in Table 3.11.

Table 17 Amoxicillin Trihydrate 250mg (DT) Sample Details and Analysis Results

No	Sample Code	Sampled from		Brand Name	Manufacturer	Batch No.	ID	Mass Uniformity	Assay	Dissolution	Appreacnce
		County	Facility								
1.	KKA/AMX/19.09.2024/013	Kakamega	Chebu Pharma Ltd	Spamox Tablets 250 DT	Sparsh Bio-Tech Pvt. Ltd	XD342	Complies	Complies	91.33%	Complies	Complies
2.	MRU/AMX/21.09.2024/015	Meru	Transwide pharmaceuticals ltd	Kemoxyl®DT 250	Laboratory & Allied Ltd.	85439	Complies	Complies	90.78%	Complies	Complies
3.	KSI/AMX/22.09.2024/021	Kisii	Nyakoe Pharmacy	Medomox 250 DT	Medopharm PVT LTD	23442006	Complies	Complies	90.48%	Complies	Complies
4.	NBI/AMX/22.09.2024/033	Nairobi	Philmed pharmaceuticals Ltd	Amoximed 250mg	Cspc Zhongnuo Phgarmazceutical (shijiazhuang),co.Ltd	79240215	Complies	Complies	90.03%	Complies	Complies

4. REGULATORY ACTIONS

The risk-based PMS identified products that did not meet the requirements of the country. Four samples analyzed (One Oxytocin sample and three Topfoliferum Tablets) failed analysis, while results of eight samples were inconclusive due to the small samples submitted for analysis. In addition, seven brands collected from the market were identified as unregistered or unauthorized by the board. The board recalled all the unregistered and samples that failed compendial testing. In addition, the superintendent pharmacists who supplied unregistered/unauthorized products into the market were summoned for disciplinary action.

No.	Product Name	API	Manufacturer	Results	Regulatory Action
1.	Alkem Metro	Metronidazole	R.K Laboratories (P) Ltd	Not registered	
2.	Amoxicillin Comprimes Dispersible A 250mg (Dt)	Amoxicillin Trihydrate BP 250mg (DT)	Medreich Ltd	Not registered	
3.	Dexamethasone	Dexamethasone Injection	Ciron Drugs & Pharmaceuticals Pvt Ltd	Not registered	
8.	Oxycop	Oxytocin	Macin Remedies India Ltd	Not registered	
9.	Tetracycline Hydrochloride Ophthalmic Ointment Usp	Tetracycline Hydrochloride Ointment	Systochem Laboratories Limited	Not registered	
10.	Unyzone	Dexamethasone Injection	Shandong Xier Kangtai Pharmaceutical Co., Ltd	Not registered	
11.	Zincopower Dt	Zinc Sulphate	Hof Pharmaceuticals Ltd	Not registered	
12.	Topfoliferum Tablets	Ferrous Sulphate & Folic Acid	Liaoning Huarui Union Pharmaceutical Co., Ltd, China	Failed test on Assay	Recalled from the market
12.	Oxytocin		Laborate Pharmaceuticals India Ltd	Failed test on related substances	Recalled from the market

5. DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.0. Discussion

Two hundred and thirteen (213) primary samples were collected from 136 facilities. These comprised 87(64%) private facilities, 46(33.8%) public facilities, and three (2.2%) Faith-Based Organizations (FBOs) spread across 37 of the 47 counties. Although the MedRS tool had prioritized 41 counties for sampling, samples were not collected from Turkana, Nyamira, Lamu and Tana River counties due to inadequate HPTs and inaccessibility of some regions.

As part of the field activity, facilities were audited for temperature and relative humidity monitoring in line with Good Storage Practices for HPTs. A total of 43 (31.6%) facilities monitored both temperature and relative humidity, while 33 (24.3%) facilities monitored temperature only. A total of 60(44.1%) facilities did not monitor environmental conditions of the storage areas. This is an area of concern that will require attention from both National and County governments.

Twenty-six (26) out of the 32 facilities where Oxytocin was sampled from monitored refrigerator temperature. The storage temperature for Oxytocin was noted to be out-of-range (2-8^{0}C) in six facilities, with the temperature ranging from -0.2^{0}C to 33^{0}C. Given the significant impact of temperature and relative humidity on the stability of HPTs, consistent monitoring and investigation of these conditions is essential.

Product registration status was verified against the Pharmacy and Poisons Board (PPB) drug registration database. Seven (12%) of the 58 product brands sampled were found to be unregistered. The board recalled all the unregistered. In addition, the superintendent pharmacists who supplied unregistered/unauthorized products into the market were summoned for disciplinary action.

All the 213 samples underwent initial physical/visual screening (Level I). Of these, 85 (39.9%) samples underwent Minilab screening (Level II), and 94 (44.1%) underwent confirmatory (Level III) testing. Kemoxyl DT (Amoxicillin Trihydrate 250mg), Manufactured by Laboratory and Allied Ltd, batch no. 85439 was doubtful during the visual and Minilab screening test characterized by yellow spots on the surface.

Ninety-four (94) samples were submitted to the PPB QCL and MEDS Laboratory for compendial testing. Of these, a total of 84 samples (89.4%) complied with specifications for all the test parameters analyzed. Oxytocin 10 IU, batch No. MOEIE-003 manufactured by Laborate Pharmaceuticals Limited, India, failed to comply with the Test for related substances. Kemoxyl DT (Amoxicillin Trihydrate 250mg) batch no. 85439, Manufactured by Laboratory and Allied Ltd, failed on its appearance. However, samples of the same batch of Kemoxyl DT collected from other sites complied with specifications for appearance. The effect of storage conditions on this could not be ruled out. A further Eight (8) samples (4 TEO & 4 Iron and Folic acid) had inconclusive results due to insufficient sample quantities to finalize all tests required.

5.1. Conclusion

A significant proportion (89.4%) of the 94 samples subjected to compendial testing conformed to the stipulated specifications. Nevertheless, certain concerns were observed. Eight samples (comprising four TEO and four iron and folic acid preparations) yielded inconclusive results due to inadequate sample quantities. Additionally, one oxytocin sample manufactured by Laborate Pharmaceuticals Limited failed the related substances test, and one Amoxycillin DT product (Kemoxyl) did not meet visual inspection criteria due to discoloration.

These findings emphasize the critical importance of sustained post-market surveillance of health products within Kenya. Such continuous monitoring is

indispensable for assuring the quality, safety, and efficacy of these products, thereby safeguarding patient health, promoting favorable treatment outcomes, and reinforcing public trust in the healthcare system. Expedient regulatory actions were initiated concerning the products that failed to meet the established standards to ensure the protection and advancement of public health and safety.

5.2. Recommendations

1. In compliance with PPB's Good Storage Practices, responsible personnel in HPT storage premises should monitor and record both the temperature and relative humidity using calibrated equipment. Routine Good Distribution Practice (GDP) inspection activities should assess and enforce compliance to this requirement.

2. County Government support supervision activities should assess and ensure compliance to Good HPT storage requirements and guidelines.

3. The personnel in pharmacies and all HPT storage areas MUST consistently comply with Manufacturer's storage recommendations for ALL HPTs.

4. Health facilities and HPT premises are encouraged to procure and use Biomedical refrigerators for storage of HPTs.

5. Prioritise Counties/ regions and HPT brands missed out in the previous PMS activities for sampling in subsequent activities.

6. Consider development of PMS plan targeting HPTs with regulatory compliance concerns

APPENDICES

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ANNEXES

Annex 1: Sample Collection Form

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Unique Sample Code ____

Transcribe the appropriate sample code in the following format: Region Initials / Molecule code/ Date samples were collected/ three-digit serial number)

e.g., NAI/GENT/05.05.2021/002

(The last 3 digits represent serialization of Samples with the first sample collected being 001, 2nd 002 etc.)

Origin of Sample

Facility Name:		Facility Code: **(Mandatory)**	

Product Details

Active Pharmaceutical Ingredient (API)/ INN Name: e.g., Amoxicillin	
Brand (Product name): (If applicable e.g., Amoxil)	

Dosage Form: (E.g., tablets/dispersible tablets, capsules, oral solution, *N/A* for medical devices)		Strength (e.g. 500 mg)	
Pack Size (e.g., 60s blister pack, 60ml bottle,100s loose)		No. of units per sample collected	
Name of Manufacturer: (e.g., Norvatis Pharma Ltd.)			
Manufacturer Address (Site of Manufacture): (e.g., Suffern, New York, USA)			
Batch or Lot #: (e.g., CF2012A4)		Date of Manufacture: (mmm/yyyy e.g., Mar/2015)	
Expiry Date: (mmm/yyyy e.g., Mar/2019)		Patient Information Leaflet Present? Yes/ No	
Manufacturer storage requirements (°C)			

Annex 2: Facility Details Form

REPUBLIC OF KENYA

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

Pharmacy and Poisons Board	**Facility Details form**	**FOM037/HPT/PDS/VMS/SOP/011**
		Rev No. 0

Facility Code **(MANDATORY)**	
County:	
Name of Facility: (Use name in MFL list if applicable)	
Sector of Facility (Public, Private, Informal)	
Type of Facility (Hospital, Health Center)	

Contact Person: (Name of respondent at facility)			
E-mail address of contact Person:		Mobile number of contact person:	
Date samples were collected at this facility (e.g., 10. 09. 2018)			
Where was the sample stored (Refrigerator, cabinet, shelf?)			
Did the fridge have fridge thermometer? YES NO			
What was the temperature recording?			
Did the storage area have a wall thermometer or thermohygrometer? YES NO			
Storage Temperature: (In area/ room where sample was picked e.g., 26.5° Celsius			
% Relative Humidity: (In area/ room where sample was picked e.g., 56.5%)			
Did the storage area have the temperature chart?			

YES	NO

Name & Signature of sample collectors:
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
Faith-based** health care facilities shall be **categorized as private

Annex 3: Oxytocin Sample Collection Form

REPUBLIC OF KENYA

MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

Unique Sample Code

____

Transcribe the appropriate sample code in the following format: Region Initials / Molecule code/ Date samples were collected/ three-digit serial number)
e.g., NBI/OXY/P or M/27.08.2024/005

(The last 3 digits represent serialization of Samples with the first sample collected being 001, 2nd 002 etc.)

Origin of Sample

Facility Name:		Facility Code: **(Mandatory)**	
Point of use where sample is collected e.g **Pharmacy** or **Maternity**			

Product Details

Active Pharmaceutical Ingredient (API)/ INN Name: e.g., Amoxicillin			
Brand (Product name): (If applicable e.g., Amoxil)			
Dosage Form: (E.g., tablets/dispersible tablets, capsules, oral solution, *N/A* for medical devices)		Strength (e.g. 500 mg)	

Pack Size (e.g., 60s blister pack, 60ml bottle,100s loose)		No. of units per sample collected	
Labelling Language			
Both primary and secondary package labebelled (yes/no)			
Name of Manufacturer and Address: (e.g., Norvatis Pharma Ltd, India.)			
Batch or Lot #: (e.g., CF2012A4)		Date of Manufacture: (mmm/yyyy e.g., Mar/2015)	
Expiry Date: (mmm/yyyy e.g., Mar/2019)		Patient Information Leaflet Present? Yes/ No	
Manufacturer storage requirements (°C)			
Where was the sample stored (Refrigerator, cabinet, shelf?)			
Did the fridge have fridge thermometer? YES NO			
What was the temperature recording?			

Annex 4: Product Information Review Form

Unique sample code _____

Product name: ____

INNs: ___

1- External packaging	**Information present on the label**
Product name	YES ☐ NO ☐
INN	YES ☐ NO ☐
Strength	YES ☐ NO ☐
Batch number	YES ☐ NO ☐
Manufacturing date	YES ☐ NO ☐
Expiry date	YES ☐ NO ☐
Manufacturer Name & Physical address	…… …… ……
Storage conditions	……
Labelling Language English / Kiswahili	YES ☐ NO ☐

2- Primary packaging	**Information present on the label**
Product name	YES ☐ NO ☐
Strength	YES ☐ NO ☐
Unit dose per blister or container stated	YES ☐ NO ☐
Batch number	YES ☐ NO ☐
Manufacturing date	YES ☐ NO ☐
Expiry date	YES ☐ NO ☐
Manufacturer name (Specify only if different from the external packaging under point 1)	YES ☐ NO ☐ ……

3- Package leaflet	

Presence of the leaflet	YES	NO	
Language(s) of the leaflet	……		
Composition	YES	NO	
Manufacturer name & physical address (Specify only if different from the external packaging under point 1)	YES ☐ NO ☐ …… ……		
Storage conditions (Specify only if different from the external packaging under point 1)	YES ☐ NO ☐ …… ……		

Annex 5: Visual and physical inspection and MiniLab results form

MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

TEST 1: VISUAL & PHYSICAL INSPECTION	
Visual Inspection:	
Please confirm that all of the recorded information in the Sample Collection Form (Annex 2) is consistent with the packaging and labeling of the medicine. Correct the Sample Collection Form (Annex 2) if there are any errors and/or omissions. Have any corrections and/or additions been made to Sample Collection Form (Annex 2): ☐ Yes ☐ No	
Other Comments (description of hologram, any print on the backing foil, etc.)	
Physical Inspection:	
Shape (circular, oval, flat sides, other)	
Uniformity of shape	
Uniformity of color	
No physical damage (cracks, breaks, erosion, abrasion, sticky)	
Other observations (no foreign contaminant, dirty marks, proper seal - for capsule)	
TEST 2: DISINTEGRATION[4]	

Time of observed disintegration (minutes) 1. _____ 2. _____ 3. _____	Did the drug pass the disintegration test? ☐ Yes ☐ No	
TEST 3: TLC		
Did the sample have a spot? ☐ Yes	Intensity of sample spot compared to standard:	
☐ No Rf Standard: _____ Rf Sample: _____ Rf % Sample difference:[5] _____	○ Less than 80% ○ Between 80% and 100% ○ More than 100% Were there any contaminants/impurities present? ☐ Yes ☐ No Observations: _____	
FINAL RESULTS		
○ The sample conformed with basic tests ○ The sample did not conform with basic tests Reason: _____ ○ The sample is considered doubtful Reason: _____		
How many units are remained after basic tests? _____		
REPORT REVIEWED BY[6]:		
Name: _____ Signature: _____ Date: _____		

[5] Rf % Sample Difference = $\frac{|\text{Rf (Standard)-Rf (Sample)}|}{\text{Rf (standard)}} \times 100$
In this formula $|Rf\ (Standard) - Rf\ (Sample)|$ represents the absolute value of the difference between the
Rf's of the standard and the sample.

Ex: In a TLC run the following values are obtained: Rf (standard) = 0,55, Rf (sample) = 0,57; The Rf % Sample

Difference = $\frac{|0.55-0.57|}{0.55} \times 100 = \frac{0.02}{0.55} \times 100 = 3.6\%$

6

If applicable

Annex 6: Analysis request form

NQCL/F 01 – 05 **ANALYSIS REQUEST FORM**

1. **Name and Address of Applicant (Company):** _____
2. **Company Tel. No. & Email Address:** _____
3. **Name and Presentation of Product:** _____
4. **Name and Address of Manufacturer:** _____ **Date of Expiry:** _____
5. **Sample Information:**
   - **a)** Date of manufacture:
   - **b)** Batch/Lot Number:
   - **c)** Name and Amount of Active Ingredients on label:
   - **d)** Quantity Submitted:
6. **Applicant's Reference Number:**
7. **Test required by applicant. Mark (□) against each test required on the table below:**

	Test	**(□)**	***Method**		**Test**	**(□)**	***Method**
1	Uniformity of Weight/ Volume			11	Water Content (Karl Fischer)		
2	Content Uniformity			12	Loss on Drying		
3	Identification			13	Optical Rotation		
4	Assay			14	Relative Density		
5	Dissolution			15	Melting Point		
6	Disintegration			16	Microbial Contamination Test		
7	Friability			17	Sterility		
8	Uniformity of Volume			18	Bacterial Endotoxin Test		
9	pH (Acidity/Alkalinity)			19	Microbial Identification		
10	Related Substances/Impurities						

If other is selected as a method please elaborate: _____

*The client must specify method of analysis to be used; U.S.P., B.P., Ph. Eur., Ph. Int., Manufacturer's Method (Please abbreviate as MoA) or Other.

Note: In all cases, preference is given to use of monographs from officially recognized current versions of pharmacopoeias (United States Pharmacopoeia (USP), British Pharmacopoeia (BP), European Pharmacopoeia (Ph. Eur.) and International Pharmacopoeia (Ph. Int.).
Clients have three days to contact NQCL if they desire to change or use a method that was not identified at the time of sample receipt.

9. **Other items submitted: Mark (□) appropriately**

CRS		**MOA & Validation Data**		**Related Substances**		**Others (specify)**	

10. **Name, Designation and Signature of Person Authorizing Request for Analysis:**

Name: _____ **Designation:** _____
Signature: _____ **Date:** _____
Contact details (Phone Number):

FOR LABORATORY USE ONLY: Payment Details

_____

_____ **Authorized by:** _____

NDQ _____

Receipt No.:		**Amount Paid:**		**Accountant:**		**Signature:**		**Date:**	

Date Received: **Received by:**

Laboratory Reference No.

Annex 7: SAMPLE RECEIVING CHECKLIST ***(For Laboratory Use Only)***

☐ **Appropriate box**

ANALYSIS REQUEST FORM

1.	Duly filled and signed in duplicate	Yes: ☐ No: ☐
2.	Appropriate tests selected as per quotation	Yes: ☐ No: ☐
3.	Right Method Indicated against each test	Yes: ☐ No: ☐

SAMPLE INSPECTION

1.	Quantity as per sample submission guidelines	Yes: ☐ No: ☐
2.	Sampling labelling requirements met (*Name, Expiry date, Batch number, label claim, Manufacturer, Manufacturer's address, Country of origin*)	Yes: ☐ No: ☐
3.	Sample packaged in a commercial pack in good condition	Yes: ☐ No: ☐
4.	Storage conditions maintained as per manufacturer's instructions	Yes: ☐ No: ☐
5.	More than 1 year remaining on shelf life	Yes: ☐ No: ☐
6.	Sample details match details filled on analysis request form	Yes: ☐ No: ☐

ACCOMPANYING DOCUMENTS

1.	Manufacturer's Method of Analysis provided	Yes: ☐ No: ☐
2.	Specifications included with the method of analysis	Yes: ☐ No: ☐
3.	Validation data on CD	Yes: ☐ No: ☐
4.	Amount paid corresponds to the Quotation provided	Yes: ☐ No: ☐

CHEMICAL REFERENCE STANDARD DETAILS

1.	Packaged in an airtight amber coloured glass bottle	Yes: ☐ No: ☐
2.	At least 6 months to expiry	Yes: ☐ No: ☐
3.	Certificate of Analysis with full details on potency, batch number and traceable to a primary standard	Yes: ☐ No: ☐
4.	Minimum amount 200 mg	Yes: ☐ No: ☐

DEVIATIONS

1.	Any deviations from the sample submission guidelines	Yes: ☐ No: ☐

If yes please give detailed reasons;

	Deviation Initiated by:	Deviation Approved by:
Name:		
Signature:		
Date:		

Annex 8: List of sampling facilities

1. EYE INFECTION

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Randomized	618627	Bamboo Health Centre	Level_3_PU Primary Hospital	Nyandarua	Kinangop
Substitute	624215	Heni Health Centre	Level_3_PU Primary Hospital	Nyandarua	Kinangop
Substitute	626689	Karangatha Health Centre	Level_3_PU Primary Hospital	Nyandarua	Kinangop
Randomized	622625	Fly Over Health Clinic	Level_3A_PR Clinics	Nyandarua	Kinangop
Substitute	617043	Pefa Mercy Mission Medical Centre	Level_3A_PR Clinics	Nyandarua	Kinangop
Substitute	617103	VESI GITHABAI NURSING HOME LIMITED	Level_3A_PR Clinics	Nyandarua	Kinangop
Randomized	639647	The Mediance Nursing Home	Level_3_PR Primary Hospital	Machakos	Yatta
Substitute	616988	Matuu Mission Health Centre	Level_3_PR Primary Hospital	Machakos	Yatta
Randomized	623542	Good Shepherd Life Care Centre(Embu)	Level_3A_PR Clinics	Embu	Manyatta
Substitute	617119	EMBU TUMAINI MEDICAL SERVICES	Level_3A_PR Clinics	Embu	Manyatta
Substitute	617542	Aga Khan University Hospital - Embu	Level_3A_PR Clinics	Embu	Manyatta
Randomized	626179	Kamelilo Dispensary	Level_3A_PU Clinics	Nandi	Tinderet
Substitute	620153	Chelambut Dispensary	Level_3A_PU Clinics	Nandi	Tinderet
Substitute	620169	Chemamul Dispensary (Tinderet)	Level_3A_PU Clinics	Nandi	Tinderet

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Randomized	636955	Sabasaba Health Centre	Level_3_PU Primary Hospital	Muranga	Kigumo
Substitute	626319	Kangari Health Centre	Level_3_PU Primary Hospital	Muranga	Kigumo
Randomized	627328	KEZA PHARMACEUTICALS LIMITED	Level_3A_PR Retail Pharmacy	Machakos	MACHAKOS
Substitute	617121	JOSKEM CHEMIST	Level_3A_PR Retail Pharmacy	Machakos	MACHAKOS
Substitute	618154	ANGYVIT PHARMACY	Level_3A_PR Retail Pharmacy	Machakos	MACHAKOS
Randomized	635471	PHARMA LIFE SCIENCE LIMITED	Level_2_PR Wholesaler	Nairobi	Westlands
Substitute	617110	BLAKLINE CONSULTING LIMITED	Level_2_PR Wholesaler	Nairobi	Westlands
Substitute	617155	4K HEALTHCARE LTD	Level_2_PR Wholesaler	Nairobi	Westlands
Randomized	626243	KAMUREITO CHEMIST	Level_3A_PR Retail Pharmacy	Bomet	Sotik
Substitute	619470	BRAMAPHOSAH AGROCHEM	Level_3A_PR Retail Pharmacy	Bomet	Sotik
Substitute	619870	CARECENT CHEMIST	Level_3A_PR Retail Pharmacy	Bomet	Sotik
Randomized	623288	Githiga Health Centre	Level_3_PU Primary Hospital	Kiambu	Githunguri
Substitute	623308	Githunguri Health Centre	Level_3_PU Primary Hospital	Kiambu	Githunguri
Substitute	626740	Karia Health Centre	Level_3_PU Primary Hospital	Kiambu	Githunguri

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Randomized	618692	Baraka Medical Clinic (Muranga North)	Level_3A_PR Clinics	Muranga	Kiharu
Substitute	616932	Imani Medical clinic	Level_3A_PR Clinics	Muranga	Kiharu
Substitute	617302	ACK Kaganda Church Dispensary	Level_3A_PR Clinics	Muranga	Kiharu
Randomized	620067	CHARAPHARM PHARMACY	Level_3A_PR Retail Pharmacy	Uasin Gishu	Soy
Substitute	618954	BETA PLUS PHARMACY	Level_3A_PR Retail Pharmacy	Uasin Gishu	Soy
Substitute	619356	BOMET CARE PHARMACEUTICALS	Level_3A_PR Retail Pharmacy	Uasin Gishu	Soy
Randomized	638784	St. Nkiria Medical Centre	Level_3_PR Primary Hospital	Migori	Kuria West
Substitute	618328	Armofron Medical Centre	Level_3_PR Primary Hospital	Migori	Kuria West
Substitute	619301	BNM	Level_3_PR Primary Hospital	Migori	Kuria West
Randomized	622346	EVAKIM PHARMACY	Level_3A_PR Retail Pharmacy	Nyeri	NYERI TOWN
Substitute	617112	AMALGAMCHEM PHARMACY	Level_3A_PR Retail Pharmacy	Nyeri	NYERI TOWN
Substitute	618944	BESTIE CARE PHARMACY	Level_3A_PR Retail Pharmacy	Nyeri	NYERI TOWN
Randomized	621256	DOPHIL NURSING AND MATERNITY HOME - PHARMACY	Level_3A_PR Clinics	Siaya	Gem
Substitute	623024	Gemifa Medical Clinic	Level_3A_PR Clinics	Siaya	Gem

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Substitute	624018	Harmony Medical Clinic	Level_3A_PR Clinics	Siaya	Gem
Randomized	627095	Keera Dispensary	Level_3A_PU Clinics	Kisii	Kitutu Chache South
Substitute	619031	Beyond Zero Medical Clinic Kisii	Level_3A_PU Clinics	Kisii	Kitutu Chache South
Substitute	619454	Bouti Dispensary	Level_3A_PU Clinics	Kisii	Kitutu Chache South
Randomized	616997	Megalife Hospital Limited	Level_3_PR Secondary Hospital	Nairobi	Kasarani
Substitute	617573	Aga Khan University Hospital(Njiru)	Level_3_PR Secondary Hospital	Nairobi	Kasarani
Substitute	636102	Radiant Group Of Hospitals Kasarani Sportsview	Level_3_PR Secondary Hospital	Nairobi	Kasarani
Randomized	638297	St Aska Medical clinic	Level_3A_PR Clinics	Migori	URIRI
Substitute	619500	BRIAN JAKE MEMORIAL HOSPITAL	Level_3A_PR Clinics	Migori	URIRI
Substitute	633624	NEOGLOBAL MEDICARE LIMITED-NURSING HOME	Level_3A_PR Clinics	Migori	URIRI
Randomized	625996	Kakuma Wellness Centre	Level_3A_PR Clinics	Turkana	Turkana West
Substitute	619204	BLISS GVS HEALTHCARE LIMITED-KAKUMA	Level_3A_PR Clinics	Turkana	Turkana West
Substitute	619243	Bliss Healthcare Limited - Kakuma	Level_3A_PR Clinics	Turkana	Turkana West
Randomized	617171	AAR Clinic Sarit Centre (Westlands)	Level_3A_PR Clinics	Nairobi	Westlands

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Substitute	616861	Centurion Pharmacy Ltd	Level_3A_PR Clinics	Nairobi	Westlands
Substitute	616921	Health AID Chemist	Level_3A_PR Clinics	Nairobi	Westlands
Randomized	640607	UZAIR PHARMA	Level_3A_PR Retail Pharmacy	Nairobi	Kamukunji
Substitute	617115	CELIK HEALTH TOURISM LIMITED	Level_3A_PR Retail Pharmacy	Nairobi	Kamukunji
Substitute	617154	4G HEALTHCARE PHARMACY LTD	Level_3A_PR Retail Pharmacy	Nairobi	Kamukunji
Randomized	640806	VITAHEALTH PHARMACY	Level_3A_PR Retail Pharmacy	Kiambu	Ruiru
Substitute	617361	AFFORD CHEMISTS	Level_3A_PR Retail Pharmacy	Kiambu	Ruiru
Substitute	617498	AFYARON PHARMACY LIMITED	Level_3A_PR Retail Pharmacy	Kiambu	Ruiru

2. ANAEMIA

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Randomized	636964	Saboti Sub County Hospital	Level_3_PU Secondary Hospital	Trans Nzoia	Saboti
Randomized	627082	Kebirigo Mission Health Centre	Level_3_PR Primary Hospital	Nyamira	Borabu
Substitute	619419	Borabu Nursing Home	Level_3_PR Primary Hospital	Nyamira	Borabu
Substitute	622258	Eronge Health Centre	Level_3_PR Primary Hospital	Nyamira	Borabu
Randomized	630349	Marble Wellness Centre	Level_3_PR Primary Hospital	Meru	Buuri West

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Substitute	616916	Gundua Health Centre	Level_3_PR Primary Hospital	Meru	Buuri West
Substitute	638854	St.Rita Hospital	Level_3_PR Primary Hospital	Meru	Buuri West
Randomized	619409	Bonyunyu prime Health Care Maternity and Nursing Home	Level_3_PR Primary Hospital	Nyamira	Nyamira North
Substitute	617435	Afya Hill Medical Centre	Level_3_PR Primary Hospital	Nyamira	Nyamira North
Substitute	621732	Ekerenyo Amani Health Centre	Level_3_PR Primary Hospital	Nyamira	Nyamira North
Randomized	626471	Kapkeringoon Dispensary	Level_3A_PR Clinics	Nandi	MOSOP
Substitute	617949	ALPHA HILL MEDICAL CENTRE LIMITED	Level_3A_PR Clinics	Nandi	MOSOP
Substitute	620284	Chepnoet Clinic	Level_3A_PR Clinics	Nandi	MOSOP
Randomized	629383	LIVINGCARE MEDICAL CENTRE	Level_3A_PR Clinics	Nyeri	NYERI TOWN
Substitute	617570	AGA KHAN UNIVERSITY HOSPITAL-NYERI	Level_3A_PR Clinics	Nyeri	NYERI TOWN
Substitute	618776	BATIAN MEDICAL SERVICES	Level_3A_PR Clinics	Nyeri	NYERI TOWN
Randomized	619309	Bodhai Dispensary	Level_3A_PU Clinics	Garissa	Hulugho
Substitute	619637	Bultohama Dispensary	Level_3A_PU Clinics	Garissa	Hulugho
Substitute	621882	Elkambere Dispensary	Level_3A_PU Clinics	Garissa	Hulugho
Randomized	616853	Brooklyn Medical Centre	Level_3A_PR Clinics	Bomet	Bomet Central
Substitute	620163	Chelymo Hospital	Level_3A_PR Clinics	Bomet	Bomet Central

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Substitute	621132	Dice icl bomet	Level_3A_PR Clinics	Bomet	Bomet Central
Randomized	626444	KAPEPHARM PHARMACY LTD	Level_3A_PR Retail Pharmacy	Laikipia	Laikipia West
Substitute	619381	BONDE CARE CHEMIST	Level_3A_PR Retail Pharmacy	Laikipia	Laikipia West
Substitute	620719	CREATION PHARMACY NYAHURURU	Level_3A_PR Retail Pharmacy	Laikipia	Laikipia West
Randomized	634271	Nyagani Dispensary	Level_3A_PR Clinics	Tharaka Nithi	Mutambi
Substitute	616984	Marima Healthcare LTD	Level_3A_PR Clinics	Tharaka Nithi	Mutambi
Substitute	618975	Bethany Medical Services	Level_3A_PR Clinics	Tharaka Nithi	Mutambi
Randomized	630319	Maragua (African Christian Churches and Schools) C	Level_3A_PR Clinics	Muranga	muranga south
Substitute	618189	Annita Medical Clinic	Level_3A_PR Clinics	Muranga	muranga south
Substitute	619128	Bishop Morrow Disp	Level_3A_PR Clinics	Muranga	muranga south
Randomized	638044	SOCH-KAA	Level_3A_PR Retail Pharmacy	Baringo	Baringo South
Substitute	622123	ENZIM PHARMACY	Level_3A_PR Retail Pharmacy	Baringo	Baringo South
Substitute	623030	GENERATION AFYA CHEMIST	Level_3A_PR Retail Pharmacy	Baringo	Baringo South
Randomized	639110	SURGIFIN LIMITED	Level_2_PR Wholesaler	Nairobi	Kamukunji
Substitute	617236	ABHA PHARMACEUTICAL LIMITED	Level_2_PR Wholesaler	Nairobi	Kamukunji
Substitute	617779	AL-HIDAYA PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Nairobi	Kamukunji

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Randomized	641410	YOSAPHARM CHEMIST	Level_3A_PR Retail Pharmacy	Uasin Gishu	Turbo
Substitute	618116	ANCHOR SOSIANI CHEMIST	Level_3A_PR Retail Pharmacy	Uasin Gishu	Turbo
Substitute	618387	ASPA PHARMACY	Level_3A_PR Retail Pharmacy	Uasin Gishu	Turbo
Randomized	639217	TAIPEI PHARMACY	Level_3A_PR Retail Pharmacy	Kisii	Nyaribari Masaba
Substitute	618187	ANNIFF CHEMIST	Level_3A_PR Retail Pharmacy	Kisii	Nyaribari Masaba
Substitute	619407	BONMED PHARMACY	Level_3A_PR Retail Pharmacy	Kisii	Nyaribari Masaba
Randomized	641137	Wema Nursing Home	Level_3_PR Primary Hospital	Nairobi	Dagoretti North
Substitute	616893	Equity Afia lavington	Level_3_PR Primary Hospital	Nairobi	Dagoretti North
Substitute	616918	Halcyon Healthcare limited	Level_3_PR Primary Hospital	Nairobi	Dagoretti North
Randomized	637337	Sawa Makutano Medical Clinic	Level_3A_PR Clinics	Machakos	Yatta
Substitute	618793	Beam health care	Level_3A_PR Clinics	Machakos	Yatta
Substitute	619003	Bethsaida Medical Clinic Yatta	Level_3A_PR Clinics	Machakos	Yatta
Randomized	636094	RACY PHARM CARE	Level_3A_PR Retail Pharmacy	Kiambu	Kikuyu
Substitute	617244	ABISHAM PHARMACY	Level_3A_PR Retail Pharmacy	Kiambu	Kikuyu
Substitute	617287	ACE CARE PHARMACEUTALS LTD	Level_3A_PR Retail Pharmacy	Kiambu	Kikuyu

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Randomized	618207	ANTIDOTE PHARMACY	Level_3A_PR Retail Pharmacy	Mombasa	Kisauni
Substitute	617874	ALIKEM PHARMACY	Level_3A_PR Retail Pharmacy	Mombasa	Kisauni
Substitute	618202	ANSELL PHARMACEUTICALS LTD BAMBURI	Level_3A_PR Retail Pharmacy	Mombasa	Kisauni
Randomized	640268	Tumaini Medical Clinic Tsangatsini	Level_3A_PR Clinics	Kilifi	KALOLENI
Substitute	617312	ACK ST. LUKES MISSION HOSPITALS LIMITED	Level_3A_PR Clinics	Kilifi	KALOLENI
Substitute	617616	Ahadi Medical Clinic	Level_3A_PR Clinics	Kilifi	KALOLENI
Randomized	628991	LATTICE CHEMIST	Level_3A_PR Retail Pharmacy	Nairobi	Roysambu
Substitute	617146	WEST CONGO PHARMACY LIMITED	Level_3A_PR Retail Pharmacy	Nairobi	Roysambu
Substitute	617656	AID MART PHARMACY	Level_3A_PR Retail Pharmacy	Nairobi	Roysambu
Randomized	619806	CALVARY HOPE MEDICAL CENTRE LTD	Level_3A_PR Clinics	Bungoma	WEBUYE WEST
Substitute	619187	BLISS GVS HEALTHCARE LIMITED - WEBUYE	Level_3A_PR Clinics	Bungoma	WEBUYE WEST
Substitute	619332	Bokoli Base Clinic	Level_3A_PR Clinics	Bungoma	WEBUYE WEST

3. <u>DIARRHOEA</u>

Category	Facility ID	Facility Name	Facility Type	County	City / Town
Randomized	627931	Kinoro Sub-County Hospital	Level_3_PU Secondary Hospital	Meru	Imenti South
Substitute	626380	Kanyakine sub County Hospital	Level_3_PU Secondary Hospital	Meru	Imenti South
Substitute	631644	Mikumbune Sub-District Hospital	Level_3_PU Secondary Hospital	Meru	Imenti South
Randomized	622286	Esiarambatsi Health Centre	Level_3_PU Primary Hospital	Vihiga	Emuhaya
Substitute	621654	Ebusiratsi Health Centre	Level_3_PU Primary Hospital	Vihiga	Emuhaya
Substitute	624863	Ipali Health Centre	Level_3_PU Primary Hospital	Vihiga	Emuhaya
Randomized	622426	Faith CFW Clinic	Level_3A_PR Clinics	Embu	RUNYENJES
Substitute	617305	ACK Macumo Icds Clinic	Level_3A_PR Clinics	Embu	RUNYENJES
Substitute	618694	Baraka Medical Clinic (Runyenjes)	Level_3A_PR Clinics	Embu	RUNYENJES
Randomized	640892	Wajir East nomadic clinic	Level_3A_PU Clinics	Wajir	Wajir East
Substitute	617359	AFARSHANLE DISPENSARY	Level_3A_PU Clinics	Wajir	Wajir East
Substitute	618293	Arbaqueranso Dispensary	Level_3A_PU Clinics	Wajir	Wajir East
Randomized	622857	Garabey Dispensary	Level_3A_PU Clinics	Garissa	Hulugho
Substitute	619309	Bodhai Dispensary	Level_3A_PU Clinics	Garissa	Hulugho
Substitute	619637	Bultohama Dispensary	Level_3A_PU Clinics	Garissa	Hulugho
Randomized	624613	Ihigaini Dispensary	Level_3A_PU Clinics	Murang a	Kangema
Substitute	622908	Gatangara Dispensary	Level_3A_PU Clinics	Murang a	Kangema
Substitute	623287	Githiga Dispensary	Level_3A_PU Clinics	Murang a	Kangema

Category	Facility ID	Facility Name	Facility Type	County	City / Town
Randomized	620242	Chepkemel Health Centre (Kericho)	Level_3_PU Primary Hospital	Kericho	Sigowet/Soin
Randomized	627517	Kibera D O Dispensary	Level_3A_PU Clinics	Nairobi	Kibra
Substitute	622989	Gatwekira B Community Clinic	Level_3A_PU Clinics	Nairobi	Kibra
Substitute	623841	Gsu Dispensary - Kibera	Level_3A_PU Clinics	Nairobi	Kibra
Randomized	631955	MOLI PHARMACY-HIBWA BLDG	Level_3A_PR Retail Pharmacy	Migori	Kuria West
Substitute	617816	ALASKA CENTRAL CHEMIST	Level_3A_PR Retail Pharmacy	Migori	Kuria West
Substitute	618854	BEMACHEM PHARMACY	Level_3A_PR Retail Pharmacy	Migori	Kuria West
Randomized	620117	Chebon Medical Clinic	Level_3A_PR Clinics	Bungoma	Mt Elgon
Substitute	620452	CHONGEWA HEALTH CENTER PHARMACY	Level_3A_PR Clinics	Bungoma	Mt Elgon
Substitute	626599	Kapsokwony Medicare	Level_3A_PR Clinics	Bungoma	Mt Elgon
Randomized	641143	WEMUR PLUS PHARMACEUTICALS	Level_3A_PR Retail Pharmacy	Kakamega	MALAVA
Substitute	617968	ALPHAED AND PHARMACEUTICAL	Level_3A_PR Retail Pharmacy	Kakamega	MALAVA
Substitute	618374	ASHULA CHEMIST	Level_3A_PR Retail Pharmacy	Kakamega	MALAVA
Randomized	617417	Afya Bora Medical Clinic (Mirangine)	Level_3A_PR Clinics	Nyandarua	Olkalou
Substitute	619221	BLISS GVS HEALTHCARE LIMITED-OL KALOU	Level_3A_PR Clinics	Nyandarua	Olkalou

Category	Facility ID	Facility Name	Facility Type	County	City / Town
Substitute	619450	Boston Medical Clinic	Level_3A_PR Clinics	Nyandarua	Olkalou
Randomized	631433	MERIDIAN MEDICAL CENTER-MACHAKOS	Level_3A_PR Clinics	Machakos	MACHAKOS
Substitute	617565	AGA KHAN UNIVERSITY HOSPITAL-MACHAKOS	Level_3A_PR Clinics	Machakos	MACHAKOS
Substitute	618138	ANGEL MEDICAL CONSULTING LTD	Level_3A_PR Clinics	Machakos	MACHAKOS
Randomized	621538	Dunga GOK Dispensary	Level_3A_PU Clinics	Kisumu	Kisumu Central
Substitute	617337	Administration Police Dispensary (Kisumu)	Level_3A_PU Clinics	Kisumu	Kisumu Central
Substitute	619032	Beyond Zero Medical Clinic(Kisumu)	Level_3A_PU Clinics	Kisumu	Kisumu Central
Randomized	623632	GOODLIFE PHARMACY LIMITED - RUBIS VALLEY ARCADE	Level_3A_PR Retail Pharmacy	Nairobi	Dagoretti North
Substitute	617218	ABAN MEDICAL SERVICES LIMITED	Level_3A_PR Retail Pharmacy	Nairobi	Dagoretti North
Substitute	617246	ABM PHARMACY LIMITED	Level_3A_PR Retail Pharmacy	Nairobi	Dagoretti North
Randomized	629844	MAESIO PHARMACEUTICAL OUTER-RING ROAD	Level_3A_PR Retail Pharmacy	Nairobi	Ruaraka
Substitute	618270	ARABICA CHEMISTS-KASARANI	Level_3A_PR Retail Pharmacy	Nairobi	Ruaraka

Category	Facility ID	Facility Name	Facility Type	County	City / Town
Substitute	618271	ARABICA CHEMISTS-LUCKY SUMMER ROAD	Level_3A_PR Retail Pharmacy	Nairobi	Ruaraka
Randomized	636171	Ramah Medical Clinic	Level_3A_PR Clinics	Kiambu	Ruiru
Substitute	616958	Kizito Medical Clinic	Level_3A_PR Clinics	Kiambu	Ruiru
Substitute	617064	Ruiru family clinic	Level_3A_PR Clinics	Kiambu	Ruiru
Randomized	620598	Coast Health Care	Level_3A_PR Clinics	Kilifi	Kilifi South
Substitute	617327	Adel Medical Clinic-	Level_3A_PR Clinics	Kilifi	Kilifi South
Substitute	617515	Aga Khan Health Services (Mtwapa)	Level_3A_PR Clinics	Kilifi	Kilifi South
Randomized	619207	BLISS GVS HEALTHCARE LIMITED-KERICHO	Level_3A_PR Clinics	Kericho	Ainamoi
Substitute	616904	Fig Tree Health Options-Kericho	Level_3A_PR Clinics	Kericho	Ainamoi
Substitute	617475	Afya Point Medicare Ltd	Level_3A_PR Clinics	Kericho	Ainamoi
Randomized	621032	DEMMY PHARM RUIRU	Level_3A_PR Retail Pharmacy	Kiambu	Ruiru
Substitute	617361	AFFORD CHEMISTS	Level_3A_PR Retail Pharmacy	Kiambu	Ruiru
Substitute	617498	AFYARON PHARMACY LIMITED	Level_3A_PR Retail Pharmacy	Kiambu	Ruiru
Randomized	619862	Care Medical Clinic	Level_3A_PR Clinics	Nakuru	Nakuru North
Substitute	617447	Afya Medical Clinic	Level_3A_PR Clinics	Nakuru	Nakuru North
Substitute	617620	Ahero Medical Clinic	Level_3A_PR Clinics	Nakuru	Nakuru North
Randomized	640409	Ukunda Diani Catholic Dispensary	Level_3A_PR Clinics	Kwale	Msambweni

Category	Facility ID	Facility Name	Facility Type	County	City / Town
Substitute	617319	Action Ministry Clinic	Level_3A_PR Clinics	Kwale	Msambweni
Substitute	617996	Alwalidayn Dispensary	Level_3A_PR Clinics	Kwale	Msambweni

4. DISEASE OF PEIPERIUM

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Randomized	632888	Mwatate Sub-District Hospital	Level_3_PU Secondary Hospital	Taita Taveta	Mwatate
Randomized	626386	Kanyangi Sub County Hospital	Level_3_PU Secondary Hospital	Kitui	Kitui Rural
Substitute	619424	Border Police Hospital (Kitui Rural)	Level_3_PU Secondary Hospital	Kitui	Kitui Rural
Randomized	623900	Habaswein District Hospital	Level_3_PU Secondary Hospital	Wajir	Wajir South
Substitute	617217	Abakore Sub District Hospital	Level_3_PU Secondary Hospital	Wajir	Wajir South
Substitute	620784	Dadajabula Sub District Hospital	Level_3_PU Secondary Hospital	Wajir	Wajir South
Randomized	634746	OLABAANI PHARMACEUTICALS LIMITED	Level_2_PR Wholesaler	Narok	Narok North
Randomized	625969	Kakamega County General Hospital	Level_3_PU Tertiary Hospital	Kakamega	Lurambi
Randomized	636280	Ravine Specialists Hospital	Level_3_PR Secondary Hospital	Baringo	Koibatek
Substitute	631398	Mercy Hospital	Level_3_PR Secondary Hospital	Baringo	Koibatek
Randomized	616836	Baraka Hospital	Level_3_PR Secondary Hospital	Narok	Narok West

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Substitute	617596	AGC Lions Ngoswani Hospital	Level_3_PR Secondary Hospital	Narok	Narok West
Randomized	633774	Ngao Sub County Hospital	Level_3_PU Secondary Hospital	Tana River	Garsen
Randomized	627158	KENDIA PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Garissa	Garissa
Substitute	620708	COUNTYLINK PHARMACEUTICAL LIMITED	Level_2_PR Wholesaler	Garissa	Garissa
Substitute	630460	MARKAZ PHARMACY	Level_2_PR Wholesaler	Garissa	Garissa
Randomized	627471	Kianyaga Sub-County Hospital	Level_3_PU Secondary Hospital	Kirinyaga	Kirinyaga East
Randomized	619668	Bura District Hospital	Level_3_PU Secondary Hospital	Garissa	Fafi
Randomized	627986	Kipkelion Sub District Hospital	Level_3_PU Secondary Hospital	Kericho	KIPKELION WEST
Substitute	622656	Forttenan Sub District Hospital	Level_3_PU Secondary Hospital	Kericho	KIPKELION WEST
Randomized	620126	CHEBU PHARMACEUTICAL LTD	Level_2_PR Wholesaler	Kakamega	MUMIAS WEST
Randomized	620974	Dawida Maternity Nursing Home	Level_3_PR Secondary Hospital	Taita Taveta	Wundanyi
Randomized	627185	KENTONS LIMITED	Level_2_PR Wholesaler	Kisumu	Kisumu West
Randomized	623420	GLOBAL NET MEDICAL LIMITED	Level_2_PR Wholesaler	Nairobi	Westlands
Substitute	617110	BLAKLINE CONSULTING LIMITED	Level_2_PR Wholesaler	Nairobi	Westlands
Substitute	617155	4K HEALTHCARE LTD	Level_2_PR Wholesaler	Nairobi	Westlands

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Randomized	636318	REAL TIME PHARMACEUTICALS LIMITED	Level_2_PR Wholesaler	Nairobi	Dagoretti North
Substitute	618404	ASTRAZENECA PHARMACEUTICALS LIMITED	Level_2_PR Wholesaler	Nairobi	Dagoretti North
Randomized	638133	Sori Lakeside Hospital (Sindo)	Level_3_PR Secondary Hospital	Homa Bay	Suba South
Substitute	631759	Misiwi Memorial Hospital	Level_3_PR Secondary Hospital	Homa Bay	Suba South
Randomized	630735	Matuu District Hospital	Level_3_PU Secondary Hospital	Machakos	Yatta
Randomized	636647	ROBREMA LTD	Level_2_PR Wholesaler	Nairobi	Embakasi East
Substitute	617393	AFRINEXT INTERNATIONAL LIMITED	Level_2_PR Wholesaler	Nairobi	Embakasi East
Substitute	618314	ARICHEM LIMITED	Level_2_PR Wholesaler	Nairobi	Embakasi East
Randomized	631055	MEDICREST PLUS LIMITED.(ACCRA ROAD)	Level_2_PR Wholesaler	Nairobi	Starehe
Substitute	617143	VEZKAM LIMITED	Level_2_PR Wholesaler	Nairobi	Starehe
Substitute	617166	A&Z NUTRACEUTICALS LIMITED	Level_2_PR Wholesaler	Nairobi	Starehe
Randomized	640083	TRANSWIDE PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Uasin Gishu	KESSES
Substitute	631160	MEDIOCARE PHARMACEUTICALS LIMITED ELDORET	Level_2_PR Wholesaler	Uasin Gishu	KESSES
Randomized	625347	JFD PHARMA LTD	Level_2_PR Wholesaler	Nairobi	Embakasi South
Substitute	617290	ACE PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Nairobi	Embakasi South

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Substitute	617960	ALPHA MEDICAL MANUFACTURERS LTD	Level_2_PR Wholesaler	Nairobi	Embakasi South
Randomized	623397	GLAD HEALTHCARE KENYA LIMITED	Level_2_PR Wholesaler	Nairobi	Kamukunji
Substitute	617236	ABHA PHARMACEUTICAL LIMITED	Level_2_PR Wholesaler	Nairobi	Kamukunji
Substitute	617779	AL-HIDAYA PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Nairobi	Kamukunji
Randomized	638819	St.Bridget Hospital-Kiambu	Level_3_PR Secondary Hospital	Kiambu	Kiambu Town
Substitute	631414	Mercylight Hospital	Level_3_PR Secondary Hospital	Kiambu	Kiambu Town
Substitute	636101	Radiant Group of Hospital (Kiambu)	Level_3_PR Secondary Hospital	Kiambu	Kiambu Town
Randomized	633951	Nightingale Medical Centre	Level_3_PR Secondary Hospital	Kisumu	Kisumu Central
Substitute	616901	Fairmont Hospital	Level_3_PR Secondary Hospital	Kisumu	Kisumu Central
Substitute	617369	Africa Inuka Hospital	Level_3_PR Secondary Hospital	Kisumu	Kisumu Central
Randomized	638875	STAMED HEALTHCARE LTD	Level_2_PR Wholesaler	Nairobi	Langata
Substitute	617213	ABAJANA LIMITED	Level_2_PR Wholesaler	Nairobi	Langata
Substitute	617281	ACCRA PHARMACY LTD	Level_2_PR Wholesaler	Nairobi	Langata
Randomized	633973	NILEPHARM EAST AFRICA LTD	Level_2_PR Wholesaler	Nairobi	Makadara
Substitute	617630	AHSAN PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Nairobi	Makadara

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Substitute	618245	APOLLO PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Nairobi	Makadara
Randomized	635801	Port Reitz Sub County Hospital	Level_3_PU Secondary Hospital	Mombasa	Changamwe
Randomized	639168	Synergy Clinics Limited-Kisumu	Level_3_PR Secondary Hospital	Kisumu	Kisumu Central
Randomized	626054	Kalimoni Hospital (Ruiru)	Level_3_PR Secondary Hospital	Kiambu	Ruiru
Substitute	618319	Arise Hospital Limited	Level_3_PR Secondary Hospital	Kiambu	Ruiru
Substitute	621672	Eddiana Hospital	Level_3_PR Secondary Hospital	Kiambu	Ruiru
Randomized	635591	PHARMAZON HEALTHCARE LIMITED	Level_2_PR Wholesaler	Nairobi	Langata
Randomized	638050	SOFITA PHARMACEUTICAL WHOLESALERS LIMITED	Level_2_PR Wholesaler	Nairobi	Dagoretti North
Randomized	639110	SURGIFIN LIMITED	Level_2_PR Wholesaler	Nairobi	Kamukunji
Randomized	638918	STATIM PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Nairobi	Westlands
Randomized	627772	Kima Mission Hospital	Level_3_PR Secondary Hospital	Vihiga	Luanda
Substitute	622136	Equater Medical Services Ekwanda	Level_3_PR Secondary Hospital	Vihiga	Luanda
Randomized	631564	MICRO LABS (EA) LTD	Level_2_PR Wholesaler	Nairobi	Westlands
Randomized	628898	Lake View Hospital	Level_3_PR Secondary Hospital	Nakuru	Naivasha

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Substitute	622600	Flamingo Medical Centre	Level_3_PR Secondary Hospital	Nakuru	Naivasha
Substitute	623493	Goldenlife Medical Centre Naivasha	Level_3_PR Secondary Hospital	Nakuru	Naivasha
Randomized	619109	BIOTECH PHARMA LTD	Level_2_PR Wholesaler	Nairobi	Westlands
Randomized	640752	VILLA SURGICAL AND EQUIPMENTS LIMITED	Level_2_PR Wholesaler	Nairobi	Kasarani
Substitute	623150	GHEMS PHARMACEUTICALS LIMITED - KANGUNDO ROAD	Level_2_PR Wholesaler	Nairobi	Kasarani
Substitute	623499	GOLDWIN PHARMA LIMITED	Level_2_PR Wholesaler	Nairobi	Kasarani
Randomized	622823	GALAXY PHARMACEUTICAL LTD - MOMBASA	Level_2_PR Wholesaler	Mombasa	Mvita
Substitute	618558	BADAR PHARMACY LTD	Level_2_PR Wholesaler	Mombasa	Mvita
Substitute	620520	CITADEL PHARMACEUTICALS LTD-DIGO RD	Level_2_PR Wholesaler	Mombasa	Mvita
Randomized	637103	SALAMA PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Nairobi	Starehe
Randomized	627205	Kenya Navy (Mir) Hospital	Level_3_PU Secondary Hospital	Mombasa	Likoni
Substitute	629278	Likoni Subcounty Hospital	Level_3_PU Secondary Hospital	Mombasa	Likoni
Substitute	632175	Mrima Maternity Hospital	Level_3_PU Secondary Hospital	Mombasa	Likoni

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Randomized	618142	ANGELICA MEDICAL SUPPLIES LTD	Level_2_PR Wholesaler	Nairobi	Dagoretti North
Substitute	618607	BALCURE PHARMACEUTICALS LIMITED	Level_2_PR Wholesaler	Nairobi	Dagoretti North
Randomized	617023	New Busia Maternity & Nursing Home	Level_3_PR Secondary Hospital	Busia	Matayos
Substitute	618012	Amane Cottage Hospital	Level_3_PR Secondary Hospital	Busia	Matayos
Substitute	623552	Goodhope Health LTD	Level_3_PR Secondary Hospital	Busia	Matayos
Randomized	617071	Shelly Beach Hospital	Level_3_PR Secondary Hospital	Mombasa	Likoni
Substitute	621118	Diani Beach Hospital	Level_3_PR Secondary Hospital	Mombasa	Likoni
Substitute	634330	Nyali Childrens Hospital	Level_3_PR Secondary Hospital	Mombasa	Likoni
Randomized	625333	Jesse Kay Hospital	Level_3_PR Secondary Hospital	Nairobi	Roysambu
Substitute	620631	Compassionate Hospital	Level_3_PR Secondary Hospital	Nairobi	Roysambu
Substitute	623069	Gertrude's Children Hospital-Thika Rd	Level_3_PR Secondary Hospital	Nairobi	Roysambu
Randomized	638294	St Antony Catholic Hospital	Level_3_PR Secondary Hospital	Nakuru	Nakuru North
Randomized	634327	Nyali Bridge Hospital	Level_3_PR Secondary Hospital	Mombasa	Kisauni
Substitute	618288	Arawa Hospital	Level_3_PR Secondary Hospital	Mombasa	Kisauni

Category	Facility Id	Facility Name	Facility Type	County	City / Town
Substitute	619028	Beyond Scope Hospital	Level_3_PR Secondary Hospital	Mombasa	Kisauni
Randomized	633184	Nakuru Nursing Home	Level_3_PR Secondary Hospital	Nakuru	Nakuru East
Substitute	617039	Our Lady Of Mercy Mission Hospital	Level_3_PR Secondary Hospital	Nakuru	Nakuru East
Substitute	617367	Afraha Maternity and Nursing Home	Level_3_PR Secondary Hospital	Nakuru	Nakuru East
Randomized	636397	Reliance Hospital Limited	Level_3_PR Secondary Hospital	Nairobi	Langata
Substitute	616962	Langata Hospital	Level_3_PR Secondary Hospital	Nairobi	Langata
Substitute	631328	Melchizedek Hospital Karen	Level_3_PR Secondary Hospital	Nairobi	Langata
Randomized	640447	Umoja Hospital	Level_3_PR Secondary Hospital	Nairobi	Embakasi West
Substitute	618571	Bahati Community	Level_3_PR Secondary Hospital	Nairobi	Embakasi West
Substitute	635458	Phadam Hospital Umoja	Level_3_PR Secondary Hospital	Nairobi	Embakasi West

5. FETAL LUNG MATURATION

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Randomized	640380	Ubuntu Hospital	Level_3_PR Secondary Hospital	Machakos	MACHAKOS
Substitute	617572	Aga Khan University Hospital(Machakos)	Level_3_PR Secondary Hospital	Machakos	MACHAKOS

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Substitute	619126	Bishop Kioko Catholic Hospital	Level_3_PR Secondary Hospital	Machakos	MACHAKOS
Randomized	633530	Nebo Hospital	Level_3_PR Secondary Hospital	Nyeri	Nyeri Central
Substitute	617040	Outspan Hospital	Level_3_PR Secondary Hospital	Nyeri	Nyeri Central
Substitute	620656	Consolata Mission Hospital (Mathari)	Level_3_PR Secondary Hospital	Nyeri	Nyeri Central
Randomized	632761	Mutuati Sub Couty Hospital	Level_3_PU Secondary Hospital	Meru	Igembe North
Randomized	631041	MEDICARE INTERNATIONAL LIMITED	Level_2_PR Wholesaler	Uasin Gishu	KAPSERET
Substitute	622400	EXPRESS MEDICINE LIMITED	Level_2_PR Wholesaler	Uasin Gishu	KAPSERET
Substitute	633639	NESHER PHARMA LIMITED	Level_2_PR Wholesaler	Uasin Gishu	KAPSERET
Randomized	628847	LABOREX KENYA LIMITED -ELDORET	Level_2_PR Wholesaler	Uasin Gishu	Turbo
Substitute	629191	LIFE CARE PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Uasin Gishu	Turbo
Substitute	633958	NILA PHARMACEUTICALS LIMITED-ELDORET	Level_2_PR Wholesaler	Uasin Gishu	Turbo
Randomized	625351	Jibana Sub District Hospital	Level_3_PU Secondary Hospital	Kilifi	KALOLENI
Substitute	630386	Mariakani District Hospital	Level_3_PU Secondary Hospital	Kilifi	KALOLENI
Randomized	618441	ATIMIROS MEMORIAL	Level_3_PR Secondary Hospital	Uasin Gishu	Moiben

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Substitute	617041	Palmcare Sinai Hospital	Level_3_PR Secondary Hospital	Uasin Gishu	Moiben
Substitute	618442	ATIMIROS MEMORIAL HOSPITAL	Level_3_PR Secondary Hospital	Uasin Gishu	Moiben
Randomized	626414	KAPA OIL REFINERIES LIMITED	Level_2_PR Wholesaler	Nairobi	Makadara
Substitute	617630	AHSAN PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Nairobi	Makadara
Substitute	618245	APOLLO PHARMACEUTICALS LTD	Level_2_PR Wholesaler	Nairobi	Makadara
Randomized	619636	BULTO SUPPLIERS & TRANSPORTERS CO. LIMITED - NAIROBI	Level_2_PR Wholesaler	Nairobi	Kibra
Substitute	625380	JITATMA PHARMA LIMITED	Level_2_PR Wholesaler	Nairobi	Kibra
Substitute	633087	NAIPHARM KENYA LIMITED	Level_2_PR Wholesaler	Nairobi	Kibra
Randomized	631277	MEDSOURCE GROUP LTD	Level_2_PR Wholesaler	Nairobi	Westlands
Substitute	617110	BLAKLINE CONSULTING LIMITED	Level_2_PR Wholesaler	Nairobi	Westlands
Substitute	617155	4K HEALTHCARE LTD	Level_2_PR Wholesaler	Nairobi	Westlands
Randomized	634941	Ongata Rongai Sub County Hospital	Level_3_PU Secondary Hospital	Kajiado	Kajiado North
Substitute	633875	Ngong Sub-County Hospital	Level_3_PU Secondary Hospital	Kajiado	Kajiado North
Randomized	629431	Lodwar County Referral Hospital	Level_3_PU Secondary Hospital	Turkana	Turkana Central

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Substitute	626289	Kanamkemer Sub County Hospital	Level_3_PU Secondary Hospital	Turkana	Turkana Central
Substitute	627203	Kenya Medical Training Collge Lodwar	Level_3_PU Secondary Hospital	Turkana	Turkana Central
Randomized	638103	SOMVEST HOLDING LTD PHARMACY	Level_2_PR Wholesaler	Nairobi	Westlands
Randomized	639841	Tigoni Sub County Hospital	Level_3_PU Secondary Hospital	Kiambu	LIMURU
Randomized	628393	KMC	Level_3_PR Secondary Hospital	Kajiado	Kajiado Central
Substitute	633214	NAMANGA NURSING HOME	Level_3_PR Secondary Hospital	Kajiado	Kajiado Central
Substitute	636290	Rayaan Hospital	Level_3_PR Secondary Hospital	Kajiado	Kajiado Central
Randomized	637378	Seaside Hospital Mariakani	Level_3_PR Secondary Hospital	Kilifi	KALOLENI
Substitute	638487	St Luke's (ACK) Nursing home Kaloleni	Level_3_PR Secondary Hospital	Kilifi	KALOLENI
Randomized	626814	Karuturi Hospital	Level_3_PR Secondary Hospital	Nakuru	Naivasha
Substitute	622600	Flamingo Medical Centre	Level_3_PR Secondary Hospital	Nakuru	Naivasha
Substitute	623493	Goldenlife Medical Centre Naivasha	Level_3_PR Secondary Hospital	Nakuru	Naivasha
Randomized	623074	Gertrudes Children Hospital	Level_3_PR Secondary Hospital	Mombasa	Nyali
Substitute	617046	Premier Hospital Limited	Level_3_PR Secondary Hospital	Mombasa	Nyali

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Substitute	617068	Sayyida Fatimah Hospital	Level_3_PR Secondary Hospital	Mombasa	Nyali
Randomized	638702	St. Ann Hospital Gathanga	Level_3_PR Secondary Hospital	Kiambu	Kiambaa
Randomized	619859	Care Hospital	Level_3_PR Secondary Hospital	Nairobi	Kamukunji
Substitute	618006	Amal hospital	Level_3_PR Secondary Hospital	Nairobi	Kamukunji
Substitute	618162	Anka Hospital	Level_3_PR Secondary Hospital	Nairobi	Kamukunji

6. PNEUMONIA UNDER FIVE YEAR CHILDREN

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Randomized	640087	TRANSWIDE PHARMACEUTICALS LTD- MERU	Level_2_PR Wholesaler	Meru	Imenti North
Substitute	620811	DAIMA DISPENSING CHEMIST LTD-MERU WHOLESALE	Level_2_PR Wholesaler	Meru	Imenti North
Substitute	629297	LIMELIGHT CHEMIST - MERU	Level_2_PR Wholesaler	Meru	Imenti North
Randomized	626048	Kaliluni (AIC) Dispensary	Level_3A_PR Clinics	Machakos	KATHIANI
Substitute	618535	AZURIE CHILDREN'S MEDICAL CENTRE LIMITED	Level_3A_PR Clinics	Machakos	KATHIANI

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Substitute	619452	Boundless Love Medicals	Level_3A_PR Clinics	Machakos	KATHIANI
Randomized	629049	Legacy Medical Centre	Level_3_PR Primary Hospital	Trans Nzoia	Kiminini
Substitute	616953	Kiminini Cottage Mission Hospital	Level_3_PR Primary Hospital	Trans Nzoia	Kiminini
Substitute	618186	Annie Hospital	Level_3_PR Primary Hospital	Trans Nzoia	Kiminini
Randomized	619662	Bungoma West Medical Services	Level_3_PR Primary Hospital	Bungoma	Kanduyi
Substitute	621845	Elgon View Medical Cottage	Level_3_PR Primary Hospital	Bungoma	Kanduyi
Substitute	622662	Fountain Healthcare Limited Bungoma	Level_3_PR Primary Hospital	Bungoma	Kanduyi
Randomized	626146	Kamayangi Dispensary	Level_3A_PU Clinics	Kitui	Mwingi North
Substitute	625931	Kairungu Dispensary (Mwingi North)	Level_3A_PU Clinics	Kitui	Mwingi North
Substitute	625947	Kaiviria Dispensary(Mwingi North)	Level_3A_PU Clinics	Kitui	Mwingi North
Randomized	620296	Chepsire Dispensary	Level_3A_PU Clinics	Nandi	Tinderet
Substitute	620153	Chelambut Dispensary	Level_3A_PU Clinics	Nandi	Tinderet
Substitute	620169	Chemamul Dispensary (Tinderet)	Level_3A_PU Clinics	Nandi	Tinderet
Randomized	639980	Toric's Nursing Home	Level_3_PR Primary Hospital	Homa Bay	Rachuonyo South
Substitute	618916	Beril's GWP Medical centre	Level_3_PR Primary Hospital	Homa Bay	Rachuonyo South

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Substitute	630252	Mangima SDA Health Centre	Level_3_PR Primary Hospital	Homa Bay	Rachuonyo South
Randomized	624736	Imara Hospital Embu (Rwika)	Level_3_PR Secondary Hospital	Embu	Mbeere South
Randomized	632849	Mwanga Medical Services	Level_3_PR Primary Hospital	Machakos	KATHIANI
Substitute	640580	Utra Kathiani Hospital	Level_3_PR Primary Hospital	Machakos	KATHIANI
Randomized	630923	Mbulutini Dispensary (Makueni)	Level_3A_PU Clinics	Makueni	Makueni
Substitute	616931	Ikalaasa dispensary	Level_3A_PU Clinics	Makueni	Makueni
Substitute	619445	Bosnia Dispensary	Level_3A_PU Clinics	Makueni	Makueni
Randomized	623974	HANMUC PHARMACY	Level_3A_PR Retail Pharmacy	Kirinyaga	NDIA
Substitute	617142	TEDDPHARM CHEMIST	Level_3A_PR Retail Pharmacy	Kirinyaga	NDIA
Substitute	618185	ANNI MEDICAL SUPPLIERS	Level_3A_PR Retail Pharmacy	Kirinyaga	NDIA
Randomized	619582	BUCKNER FAMILY HOPE CLINIC - BUNGOMA	Level_3A_PR Clinics	Bungoma	Sirisia
Substitute	617163	A.C.K Butonge Dispensary	Level_3A_PR Clinics	Bungoma	Sirisia
Substitute	619581	Buckner Clinic	Level_3A_PR Clinics	Bungoma	Sirisia
Randomized	631734	MIRIRI PHARMACY	Level_3A_PR Retail Pharmacy	Mombasa	Kisauni
Substitute	617874	ALIKEM PHARMACY	Level_3A_PR Retail Pharmacy	Mombasa	Kisauni

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Substitute	618202	ANSELL PHARMACEUTICALS LTD BAMBURI	Level_3A_PR Retail Pharmacy	Mombasa	Kisauni
Randomized	632225	Mt. Kenya Kangema Hospital Limited	Level_3A_PR Clinics	Muranga	Kangema
Substitute	617458	Afya Medical Clinic (Muranga North)	Level_3A_PR Clinics	Muranga	Kangema
Substitute	622586	Firstcare Medical Clinic	Level_3A_PR Clinics	Muranga	Kangema
Randomized	618835	BELGUT CHEMIST-KERICHO	Level_3A_PR Retail Pharmacy	Kericho	Ainamoi
Substitute	617481	AFYACARE PHARMACY KERICHO	Level_3A_PR Retail Pharmacy	Kericho	Ainamoi
Substitute	617495	AFYAPOINT MEDICARE LIMITED	Level_3A_PR Retail Pharmacy	Kericho	Ainamoi
Randomized	630862	Mbale Specialist Health Centre	Level_3_PR Primary Hospital	Vihiga	VIHIGA
Randomized	632625	Murunyu Dispensary	Level_3A_PU Clinics	Nakuru	Nakuru North
Substitute	623067	Gerol Dispensary	Level_3A_PU Clinics	Nakuru	Nakuru North
Substitute	628367	Kiwamu Dispensary	Level_3A_PU Clinics	Nakuru	Nakuru North
Randomized	620205	Chemoril dispensary	Level_3A_PU Clinics	Baringo	Tiaty
Substitute	620238	Chepkalacha Dispensary	Level_3A_PU Clinics	Baringo	Tiaty
Substitute	620376	Chesirimion Dispensary	Level_3A_PU Clinics	Baringo	Tiaty
Randomized	621107	DIADEMS PHARMACY	Level_2_PR Wholesaler	Kajiado	Kajiado North
Substitute	624934	ISOPHARM LIMITED	Level_2_PR Wholesaler	Kajiado	Kajiado North
Substitute	631263	MEDS AND ALLIED	Level_2_PR Wholesaler	Kajiado	Kajiado North

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
		SERVICES LIMITED			
Randomized	623377	GK Prison Dispensary (Thika)	Level_3A_PU Clinics	Kiambu	Ruiru
Substitute	623376	GK Prison Dispensary (Ruiru)	Level_3A_PU Clinics	Kiambu	Ruiru
Substitute	632758	Mutonya Dispensary	Level_3A_PU Clinics	Kiambu	Ruiru
Randomized	620892	DANNES PHARMACY LTD	Level_2_PR Wholesaler	Nairobi	Embakasi East
Substitute	617393	AFRINEXT INTERNATIONAL LIMITED	Level_2_PR Wholesaler	Nairobi	Embakasi East
Substitute	618314	ARICHEM LIMITED	Level_2_PR Wholesaler	Nairobi	Embakasi East
Randomized	620782	Dadaab Sub-County Hospital	Level_3_PU Secondary Hospital	Garissa	Dadaab
Substitute	624579	Ifo 2 Hospital	Level_3_PU Secondary Hospital	Garissa	Dadaab
Randomized	637114	SALCARE CHEMIST	Level_3A_PR Retail Pharmacy	Nakuru	Rongai
Substitute	617473	AFYA NYCE	Level_3A_PR Retail Pharmacy	Nakuru	Rongai
Substitute	618909	BENSY PHARMACY	Level_3A_PR Retail Pharmacy	Nakuru	Rongai
Randomized	634763	OLD MADARAKA CHEMIST LTD	Level_3A_PR Retail Pharmacy	Kilifi	KILIFI NORTH
Substitute	617349	ADVACARE CHEMISTS	Level_3A_PR Retail Pharmacy	Kilifi	KILIFI NORTH
Substitute	617376	AFRICARE CHEMIST	Level_3A_PR Retail Pharmacy	Kilifi	KILIFI NORTH

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Randomized	634812	Olivelink Healthcare Limited	Level_3_PR Primary Hospital	Nairobi	Embakasi East
Substitute	617045	Penda health limited tassia	Level_3_PR Primary Hospital	Nairobi	Embakasi East
Substitute	617100	Utawala Estate Health Centre	Level_3_PR Primary Hospital	Nairobi	Embakasi East
Randomized	633870	Ngondu Medical Clinic	Level_3A_PR Clinics	Nakuru	Njoro
Substitute	618896	Benmac Clinic	Level_3A_PR Clinics	Nakuru	Njoro
Substitute	618897	BENMAC CLINIC PHARMACY	Level_3A_PR Clinics	Nakuru	Njoro
Randomized	630984	MEDBRIDGE CHEMIST-NAKURU	Level_3A_PR Retail Pharmacy	Nakuru	NAKURU TOWN WEST
Substitute	617710	AKOEMED CHEMIST AND COSMETICS	Level_3A_PR Retail Pharmacy	Nakuru	NAKURU TOWN WEST
Substitute	617829	ALCONN PHARMACY	Level_3A_PR Retail Pharmacy	Nakuru	NAKURU TOWN WEST
Randomized	628005	KIPLOMBE MED PHARMACY	Level_3A_PR Clinics	Uasin Gishu	Soy
Substitute	617173	AAR Eldoret	Level_3A_PR Clinics	Uasin Gishu	Soy
Substitute	618112	Anama Medical Clinic	Level_3A_PR Clinics	Uasin Gishu	Soy
Randomized	636189	Ramos Medical Clinic	Level_3A_PR Clinics	Kiambu	Kabete
Substitute	617262	Abundant Medical Clinic	Level_3A_PR Clinics	Kiambu	Kabete
Substitute	617285	Accucare Clinic and Home Based Nursing	Level_3A_PR Clinics	Kiambu	Kabete
Randomized	636320	REALE HOSPITAL CLINIC ELDORET	Level_3A_PR Clinics	Uasin Gishu	KESSES
Substitute	617239	Abigael Health Care Centre	Level_3A_PR Clinics	Uasin Gishu	KESSES

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Substitute	618548	Babra Medical Clinic	Level_3A_PR Clinics	Uasin Gishu	KESSES
Randomized	629970	Maji Ya Chumvi Dispensary	Level_3A_PU Clinics	Kwale	KINANGO
Substitute	619125	Bishop Kalu Dispensary	Level_3A_PU Clinics	Kwale	KINANGO
Substitute	619316	Bofu Dispensary	Level_3A_PU Clinics	Kwale	KINANGO
Randomized	639006	SUHEYLA PHARMACEUTICALS & MEDICAL SERVICES	Level_3A_PR Retail Pharmacy	Lamu	LAMU WEST
Substitute	617689	AJMU MPEKETONI CHEMIST	Level_3A_PR Retail Pharmacy	Lamu	LAMU WEST
Substitute	617766	AL-BIRR PHARMACY	Level_3A_PR Retail Pharmacy	Lamu	LAMU WEST
Randomized	622541	FENACARE PHARMACY	Level_3A_PR Retail Pharmacy	Nairobi	Embakasi South
Substitute	617750	AL XAYAAT PHARMACY AND COSMETICS LIMITED	Level_3A_PR Retail Pharmacy	Nairobi	Embakasi South
Substitute	617898	ALLAMED PHARMACEUTICALS LIMITED	Level_3A_PR Retail Pharmacy	Nairobi	Embakasi South
Randomized	626629	KAPTICH CHEMIST LIMITED	Level_3A_PR Retail Pharmacy	West Pokot	POKOT SOUTH
Substitute	618807	BEEMED PHARMACY	Level_3A_PR Retail Pharmacy	West Pokot	POKOT SOUTH
Substitute	627993	KIPKOMO CHEMIST	Level_3A_PR Retail Pharmacy	West Pokot	POKOT SOUTH
Randomized	625457	JONYA CHEMIST	Level_3A_PR Retail Pharmacy	Kisii	Bobasi
Substitute	620190	CHEMIN PHARMACY	Level_3A_PR Retail Pharmacy	Kisii	Bobasi

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Substitute	629295	LIMCHEM PHARMACY	Level_3A_PR Retail Pharmacy	Kisii	Bobasi
Randomized	617637	AIC Ebenezer	Level_3A_PR Clinics	Baringo	Baringo Central
Substitute	618733	BARNET MEMORIAL MEDICAL CENTRE	Level_3A_PR Clinics	Baringo	Baringo Central
Substitute	619190	BLISS GVS HEALTHCARE LIMITED KABARNET	Level_3A_PR Clinics	Baringo	Baringo Central
Randomized	626196	Kamlesh Kapadia Optics Limited-Westlands	Level_3A_PR Clinics	Nairobi	Westlands
Substitute	616861	Centurion Pharmacy Ltd	Level_3A_PR Clinics	Nairobi	Westlands
Substitute	616921	Health AID Chemist	Level_3A_PR Clinics	Nairobi	Westlands
Randomized	625473	JORRYCHEM MEDICAL PHARMACY	Level_3A_PR Retail Pharmacy	Kwale	Msambweni
Substitute	617678	AIRSTRIP ROAD CHEMIST	Level_3A_PR Retail Pharmacy	Kwale	Msambweni
Substitute	617922	ALLYWAYS PHARMACY	Level_3A_PR Retail Pharmacy	Kwale	Msambweni
Randomized	637275	SAPTA Nasra	Level_3A_PR Clinics	Nairobi	Embakasi Central
Substitute	616889	Equity Afia Kayole	Level_3A_PR Clinics	Nairobi	Embakasi Central
Substitute	617541	Aga Khan University Hosp Mother & Child Clinic	Level_3A_PR Clinics	Nairobi	Embakasi Central
Randomized	625438	Joma Medical Centre	Level_3A_PR Clinics	Nairobi	Roysambu
Substitute	617120	EQUITY AFIA ROYSAMBU	Level_3A_PR Clinics	Nairobi	Roysambu

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Substitute	617193	AAR HEALTHCARE LTD-ROYSAMBU	Level_3A_PR Clinics	Nairobi	Roysambu

7. VITAMIN DEFICIENCY BLEEDING

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Randomized	622533	Faza Hospital	Level_3_PU Secondary Hospital	Lamu	Lamu East
Randomized	624049	Haven Hospital	Level_3_PR Secondary Hospital	Siaya	Bondo
Substitute	629927	Mainland Relief Hospital	Level_3_PR Secondary Hospital	Siaya	Bondo
Substitute	636046	Queenteric Annex Hospital	Level_3_PR Secondary Hospital	Siaya	Bondo
Randomized	632166	Mpeketoni Sub-County Hospital	Level_3_PU Secondary Hospital	Lamu	LAMU WEST
Randomized	640898	Wajir TB Manyatta Sub County Hospital	Level_3_PU Secondary Hospital	Wajir	Wajir East
Substitute	627358	Khorof Harar Sub County Hospital	Level_3_PU Secondary Hospital	Wajir	Wajir East
Substitute	640891	Wajir County Referral Hospital	Level_3_PU Secondary Hospital	Wajir	Wajir East
Randomized	624776	IMPERIAL MANAGED SOLUTIONS EAST AFRICA LTD-MLOLONGO	Level_2_PR Wholesaler	Machakos	MAVOKO
Substitute	619112	BIOVAIL PHARMACEUTICAL LIMITED	Level_2_PR Wholesaler	Machakos	MAVOKO
Substitute	619769	BWOSI INVESTMENTS	Level_2_PR Wholesaler	Machakos	MAVOKO

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Randomized	622409	F & K PHARMA LTD	Level_2_PR Wholesaler	Nairobi	Starehe
Substitute	617143	VEZKAM LIMITED	Level_2_PR Wholesaler	Nairobi	Starehe
Substitute	617166	A&Z NUTRACEUTICALS LIMITED	Level_2_PR Wholesaler	Nairobi	Starehe
Randomized	618314	ARICHEM LIMITED	Level_2_PR Wholesaler	Nairobi	Embakasi East
Substitute	617393	AFRINEXT INTERNATIONAL LIMITED	Level_2_PR Wholesaler	Nairobi	Embakasi East
Substitute	618454	AUTOSTERILE (EA) LIMITED	Level_2_PR Wholesaler	Nairobi	Embakasi East
Randomized	619313	BOEHRINGER INGELHEIM MIDDLE EAST AND AFRICA SCIENTIFIC OFFICE KENYA	Level_2_PR Wholesaler	Nairobi	Langata
Substitute	617213	ABAJANA LIMITED	Level_2_PR Wholesaler	Nairobi	Langata
Substitute	617281	ACCRA PHARMACY LTD	Level_2_PR Wholesaler	Nairobi	Langata
Randomized	624508	Huruma District Hospital	Level_3_PU Secondary Hospital	Uasin Gishu	Turbo
Substitute	640296	Turbo Sub County Hospital	Level_3_PU Secondary Hospital	Uasin Gishu	Turbo
Randomized	635252	Pastor Machage Memorial Hospital	Level_3_PR Secondary Hospital	Migori	Suna West
Substitute	616967	LifeCare Hospital Migori	Level_3_PR Secondary Hospital	Migori	Suna West
Substitute	634724	Ojele Memorial Hospital	Level_3_PR Secondary Hospital	Migori	Suna West
Randomized	638489	St Luke's Hospital	Level_3_PR Secondary Hospital	Kisumu	Kisumu Central

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Substitute	616901	Fairmont Hospital	Level_3_PR Secondary Hospital	Kisumu	Kisumu Central
Substitute	617369	Africa Inuka Hospital	Level_3_PR Secondary Hospital	Kisumu	Kisumu Central
Randomized	617052	Randburg Community Hospital	Level_3_PR Secondary Hospital	Kisumu	Nyando
Randomized	625380	JITATMA PHARMA LIMITED	Level_2_PR Wholesaler	Nairobi	Kibra
Substitute	619636	BULTO SUPPLIERS & TRANSPORTERS CO. LIMITED - NAIROBI	Level_2_PR Wholesaler	Nairobi	Kibra
Substitute	633087	NAIPHARM KENYA LIMITED	Level_2_PR Wholesaler	Nairobi	Kibra
Randomized	629266	LIGNUM VITAEHEALTH KENYA LIMITED	Level_2_PR Wholesaler	Nairobi	Langata
Randomized	635874	PRIME HEALTH PHARMA LIMITED	Level_2_PR Wholesaler	Nairobi	Westlands
Substitute	617110	BLAKLINE CONSULTING LIMITED	Level_2_PR Wholesaler	Nairobi	Westlands
Substitute	617155	4K HEALTHCARE LTD	Level_2_PR Wholesaler	Nairobi	Westlands
Randomized	620735	CRISBIO PHARMACEUTICAL LIMITED-NAKURU TOWN	Level_2_PR Wholesaler	Nakuru	NAKURU TOWN WEST
Substitute	635768	PONDERS, LIMITED.	Level_2_PR Wholesaler	Nakuru	NAKURU TOWN WEST

Category	Facility ID	Facility Name	Facility Type	County	City/ Town
Randomized	631969	Mombasa Breeze Hospital	Level_3_PR Secondary Hospital	Mombasa	Mvita
Substitute	617000	Mewa Hospital	Level_3_PR Secondary Hospital	Mombasa	Mvita
Substitute	617042	Pandya Memorial Hospital	Level_3_PR Secondary Hospital	Mombasa	Mvita
Randomized	634974	Optimum Current Health Care Hospital	Level_3_PR Secondary Hospital	Nakuru	Nakuru East
Substitute	617039	Our Lady Of Mercy Mission Hospital	Level_3_PR Secondary Hospital	Nakuru	Nakuru East
Substitute	617367	Afraha Maternity and Nursing Home	Level_3_PR Secondary Hospital	Nakuru	Nakuru East
Randomized	636106	RADIANT GROUP OF HOSPITALS-UMOJA	Level_3_PR Secondary Hospital	Nairobi	Embakasi West
Substitute	618571	Bahati Community	Level_3_PR Secondary Hospital	Nairobi	Embakasi West
Substitute	635458	Phadam Hospital Umoja	Level_3_PR Secondary Hospital	Nairobi	Embakasi West
Randomized	638508	St Marks Hospital	Level_3_PR Secondary Hospital	Kiambu	Kiambu Town
Substitute	631414	Mercylight Hospital	Level_3_PR Secondary Hospital	Kiambu	Kiambu Town
Substitute	636101	Radiant Group of Hospital (Kiambu)	Level_3_PR Secondary Hospital	Kiambu	Kiambu Town