A critical look at the quality concerns and the role of county governments in ensuring that health products and technologies used in service delivery are safe.

Background

The quality of Health Products and Technologies (HPT) in the Country remains an important subject of debate given that their quality is just as critical if the highest attainable quality healthcare must be achieved for all. While drugs and medical devices go through robust manufacturing processes, quality assurance and control as well as purposeful/targeted post market follow-ups to assure quality, their complexity and use is increasingly expanding with advances in technology. Equally, substandard, and falsified HPT are globally on the increase and pose catastrophic health threats and far greater health implications and economic losses to a Country. The County governments responsible for the provision of health services must seek to always sustain access to high quality HPT, and, at reasonable costs affordable to them especially when procuring outside the Kenya Medical Supplies Agency when demand calls. Therefore, the need for county governments to be effectively engaged and aware of the status of quality of HPT is very critical to inform decision making under the devolved system of governance. This paper looks at the opportunities for county governments in this space and focuses on both pre and post market quality monitoring for HPT in Kenya.

County Governments: Paying due diligence in procuring HPT from sources registered by the regulator for quality and traceability is key https://products.pharmacyboardkenya.org/ppb_admin/pages/review_retention_products_public_php

Methodology

Review of literature on quality of HPT in the Country was carried out. Both published and non-published material and program reports were utilized. Available data was analyzed to provide insights into and validate the available literature.

Objective

The main objective was to.

1. Assess the situation of both pre and post market quality monitoring for HPT in Kenya with a view to identifying gaps and risks for County Governments.
2. Examine the extent of quality monitoring across HPT categories to appreciate the in-country capacity and existing opportunities for improvements
3. Identify the different roles of stakeholders within the HPT quality monitoring space and the level of engagement with County Governments who are key stakeholders and consumers of HPT

Quality assurance mechanisms

The Pharmacy and Poisons Board carries out quality control monitoring for HPT to safeguard users, and registers[1] HPT upon satisfying safety, efficacy, quality, and economic value concerns. The regulator, accordingly, utilizes testing laboratories, both locally and internationally, and a set of mechanisms, as the basis for registration and regulation of the manufacture, import, and trade in quality HPT. There is a significant gap with limited local manufacturing sites registered from within the country. County governments keen on facilitating and supporting local production will need to focus on quality too.

At least 6,475 products were retained in the PPB register by the year 2021. Consequently, 43 local and 1315 foreign manufacturing sites received approval certificates to trade in HPT in Kenya, respectively

Routine laboratory testing for HPT in Kenya

Table 1: Failure rates of samples tested at NQCL 2018 and 2019

NATIONAL QUALITY CONTROL LAB		
Description	**2018**	**2019**
No. of samples analysed	787	836
No. of compliant samples	743	827
No. of non-compliant samples	44	9
PASS RATE	**94%**	**99%**
FAILURE RATE	**6%**	**1%**

The figure 1 and 2 below shows samples tested at the Mission for Essential Drugs and supplies (MEDS) laboratory between 1997 and 2019 with corresponding significant decline in sample failure rate from 13.2% in 1997 to a sample failure rate of 1.5% in 2019. (Figure 2). County governments are assured of the quality of health products in the market, however, the storage infrastructure

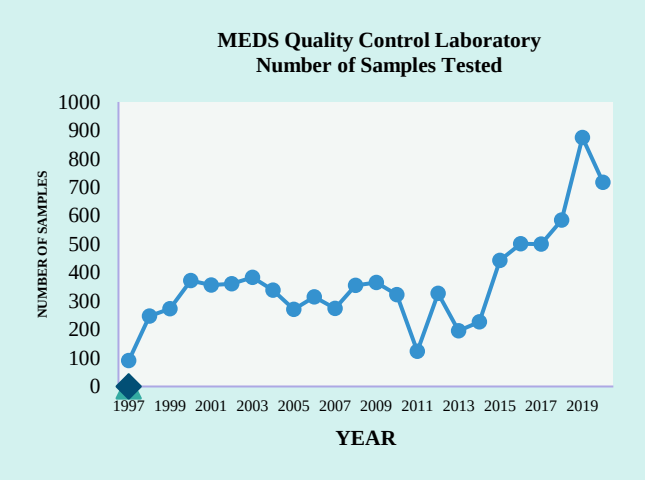


Figure 1: Number of samples tested at MEDS 1997-2019

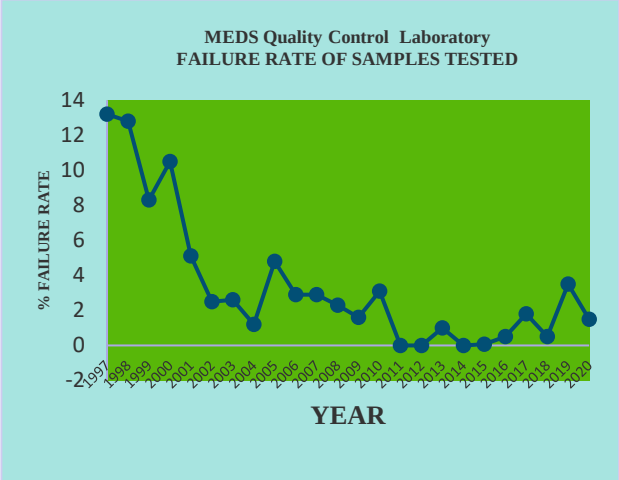


Figure 2: Failure rates of samples tested at MEDS 1997-2019

Post market quality monitoring for strategic commodities HPT in Kenya

Despite the cost in absolute terms, PMS has been very essential in combating substandard and falsified HPT in the market and is considered an essential and cost-efficient means of detecting and minimizing injury to patients and averting potential disaster[2]

[1] Pharmacy and Poisons Act, CAP 244
[2] WHO 2006

A single PMS activity has been estimated to cost up to 40 million Ksh with half the projected costs going into product testing/laboratory analysis. The average cost of testing per sample is 1,000 USD in the public laboratory and this varies with the type and number of test parameters requested. The testing costs ranges between 800USD and 1350 USD

Strategic commodities: The results for malaria indicate an improvement in sample pass rate from 84% to 100% between 2010 and 2019. Similarly, the presence of unregistered antimalarials in the market reduced from 7% to 1% during the same period. An annual PMS activity in 2019 conducted for ARVs, Anti TBs and antimalarials had all samples (209) analyzed comply[3] with the specifications. County governments too, have a great opportunity to ensure products procured can be regularly tested to ascertain quality where in doubt. Storage infrastructure and storage practices have been cited by the regulator as one of the factors contributing to high failure rates in PMS samples, as compared to other factors.

Post market quality monitoring for Essential HPT in Kenya

	Analytical Tests Performed									
	Uniformity of Weight		Identification		Dissolution		Assay		pH	
	Compliant	Non-Compliant	Compliant	Non-Compliant	Compliant	Non-Compliant	Compliant	Non-Compliant	Compliant	Non-Compliant
Albendazole Tablets	9	0	9	0	2	7	9	0	-	-
Albendazole Susps	-	-	10	0	-	-	10	0	10	0
Amoxicillin Capsules	22	0	22	0	22	0	22	0	-	-
Amoxicillin Susps	-	-	13	0	-	-	12	1	13	0
Amoxicillin Tablets	5	0	5	0	4	1	5	0	-	-
Ciprofloxacin Tablets	21	0	21	0	19	2	21	0	-	-
Enalapril Tablets	13	0	13	0	12	1	10	3	-	-
Folic acid Tablets	7	0	7	0	7	0	7	0	-	-
Folic acid/$FeSO_4$ Tabs	5	0	5	0	5	0	2	3	-	-
Glibenclamide Tablets	13	0	13	0	13	0	13	0	-	-
Hydrochlorothiazide	15	0	15	0	15	0	15	0	-	-
Levonorgestrel Tabs	12	0	12	0	12	0	12	0	-	-
Metformin Tablets	14	0	14	0	14	0	14	0	-	-
Paracetamol Tablets	15	2	17	0	16	1	17	0	-	-
Paracetamol Susps	-	-	16	0	-	-	16	0	16	0
Sildenafil Tablets	9	1	10	0	10	0	9	1	-	-
Sildenafil Soft-Gel	1	0	1	0	-	-	1	0	-	-
Total	161	3	203	0	151	12	195	8	39	0
% Compliance	98.2%	1.8%	100.0%	0.0%	92.6%	7.4%	96.1%	3.9%	100.0%	0.0%

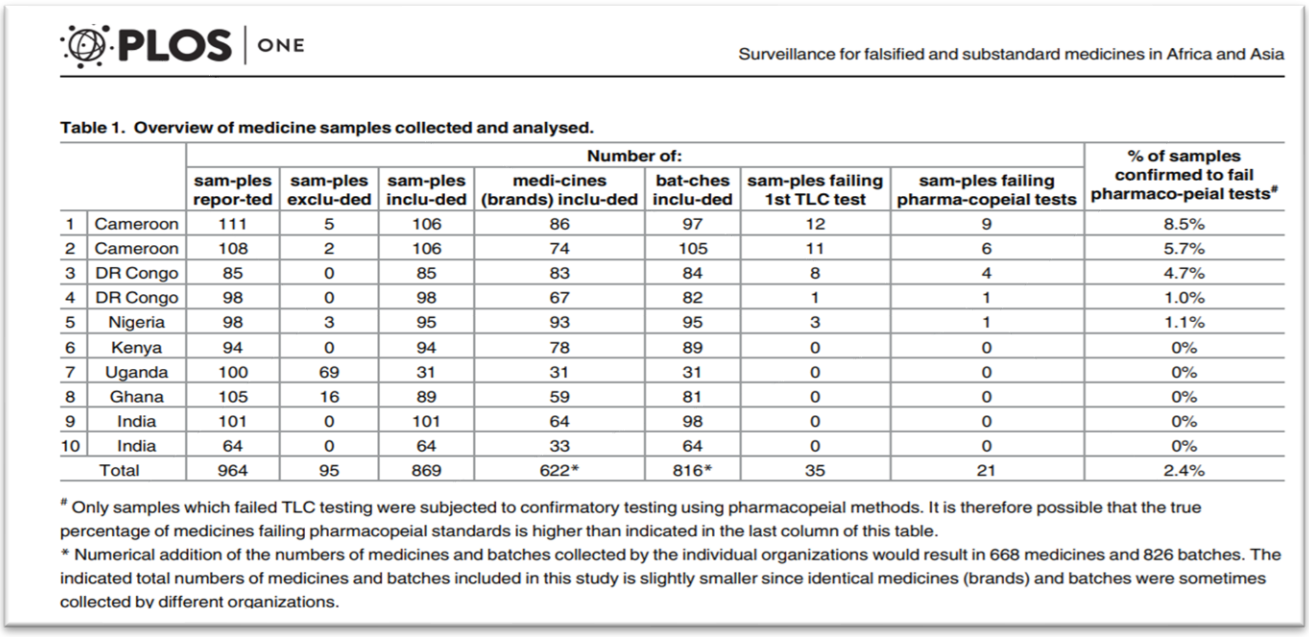
Table 2: Summary of compliance status -Source NQCL 2019 report on Post market surveillance of HPT

The quality monitoring for essential HPT has been inadequate with testing largely limited to the analysis of ad hoc reported substandard or falsified samples arising from the public or provider complaints. Nevertheless, the table 2 above and figure 3 below, both showing compliance status for two recent, yet independent, internal, and external PMS results for essential HPT, give some level of confidence in the quality of products in the market.

However, the 2019 PMS report for essential HPT also indicates that 14% of essential products are unregistered, where condoms (35%) and syringes (53.6%) comprised, the highest unregistered products underscoring the importance of heightened vigilance. Only 67.5% of the 785 samples collected were stored appropriately in the sampled facilities indicating a need to improve HPT storage infrastructure in the country.

[3] 2019 Joint PMS Report for HIV/AIDS, Tuberculosis and Malaria

Comparison with other countries across the region



PLOS ONE | Surveillance for falsified and substandard medicines in Africa and Asia

Table 1. Overview of medicine samples collected and analysed.

		Number of:							% of samples confirmed to fail pharmaco-peial tests[#]
		sam-ples repor-ted	sam-ples exclu-ded	sam-ples inclu-ded	medi-cines (brands) inclu-ded	bat-ches inclu-ded	sam-ples failing 1st TLC test	sam-ples failing pharma-copeial tests	
1	Cameroon	111	5	106	86	97	12	9	8.5%
2	Cameroon	108	2	106	74	105	11	6	5.7%
3	DR Congo	85	0	85	83	84	8	4	4.7%
4	DR Congo	98	0	98	67	82	1	1	1.0%
5	Nigeria	98	3	95	93	95	3	1	1.1%
6	Kenya	94	0	94	78	89	0	0	0%
7	Uganda	100	69	31	31	31	0	0	0%
8	Ghana	105	16	89	59	81	0	0	0%
9	India	101	0	101	64	98	0	0	0%
10	India	64	0	64	33	64	0	0	0%
	Total	964	95	869	622*	816*	35	21	2.4%

[#] Only samples which failed TLC testing were subjected to confirmatory testing using pharmacopeial methods. It is therefore possible that the true percentage of medicines failing pharmacopeial standards is higher than indicated in the last column of this table.

* Numerical addition of the numbers of medicines and batches collected by the individual organizations would result in 668 medicines and 826 batches. The indicated total numbers of medicines and batches included in this study is slightly smaller since identical medicines (brands) and batches were sometimes collected by different organizations.

Figure 1: Results for Surveillance for falsified and substandard medicines in Africa and Asia[4]

Pharmacovigilance and Post Market Surveillance for HPT

Cumulatively Kenya reported a total of 14,403 (0.06%) to the global data information pool of 23,609,664 for adverse drug events. Since 2017, on average, at least 56.4% of the Counties report on ADRs with Nairobi County leading in the numbers reported (Range 25.5 – 95.5%). Although over 70% or reported ADRs are not life threatening, about 8.8% result in death in Kenya. It is important to note that substandard and falsified HPT have an increased risk of causing ADRs. Both international pharma intelligence and country data has contributed greatly to informing Kenya's pharma vigilance and heightened reporting by county facilities will enhance wide information sharing on product safety and use.

In-Country HPT quality control and testing capabilities

The local capacity for quality monitoring has improved over time and Kenya has two quality control and testing laboratories for HPT that are pre-qualified by the World Health Organization, one in public and the other in private sector. Over and above, the regulator also employs mobile laboratories duped minilabs, collaborates with other quality control laboratories e.g., Kenya National Bureau of Standards (KNBS), the Kenya Medical Research Institute (KEMRI), Kenya Medical Supplies Agency (KEMSA) and private testing laboratories (pharmaceutical manufacturing industries as well as standalone laboratories).

[4] The products collected in Kenya included the following classes: antibacterial (46), antiprotozoal (13); analgesics (6); antihelminth (7); antimycobacterial (4); antidiabetics (4); for obstructive airway diseases treatment (2); beta blocking agents (6); diuretics (2); corticosteroids for systemic use (2) and hormonal modulators of genital system (2). Although the specific molecules are not specified, this represents a wide scope of essential medicines in the market.

Product Category	Product -Subcategory	In Country Capacity to Test	Pre-Market	Post Market	Comments
Pharmaceuticals (Medicines)	Essential drugs: Antihypertensives, Anticonvulsants, anticoagulants, Antidiabetics, corticosteroids, Diuretics, antibacterial, antihelminth, etc.	YES	YES	Full capacity for PMS	-Both NQCL and MEDs have capacity to test -Need to expand scope of PMS for essential medicines tested based on a risk approach -Some extensive post-market quality surveys for these products have been done
	Anticancer **Anticancer – Biologicals**	YES	YES	Capacity in place	-Both NQCL and MEDs have capacity to test -Adequate funding required for PMS activities – procurement of samples very expensive
		Limited	Limited	Limited	Need to build capacity
	ARVs	YES	YES	YES	-Both NQCL and MEDs have capacity to test
	AntiTBs	YES	YES	YES	-Both NQCL and MEDs have capacity to test
	Antimalarials	YES	YES	YES	A series of PMS have been carried out on antimalarials and indicate reliable quality
	RH products				-Both NQCL and MEDs have capacity to test
	Vaccines – Including COVID-19	Limited	Limited	Limited	Utilizes procurement from WHO prequalified manufacturers to mitigate on quality.
Sports and Nutrition commodities	Therapeutic feeds	YES	YES	LIMITED	KEBS; -Need for nutrition products targeted PMS
	Supplements including for sports				**KEBS**
Non pharmaceuticals	PPE - Overalls	YES	YES	**TBD**	**KEBS; -**PMS for PPE not yet done
	PPE - Face masks	YES	YES	**TBD**	**KEBS** -PMS for PPEs not yet done
	Syringes	YES	YES	Capacity in place	-NQCL has capacity to test. -Few PMS surveys done on this product category. -Need to prioritize more PMS
	Gloves	YES	YES	Capacity in place	-NQCL has capacity to test; -Few PMS surveys done on this product category; -Need to prioritize more PMS
	Needles	YES	YES	Capacity in place	-NQCL has capacity to test; -Few PMS surveys done on this product category; -Need to prioritize more PMS
	Condoms (Female and male latex condoms)	YES	YES	Capacity in place	-NQCL has capacity to test; -Few PMS surveys done on this product category; A condom PMS RRI done in 2019 with detection of poor-quality samples
	Other non-pharmaceuticals	Limited	Limited	Limited	
Lab Diagnostics	RDTs - Malaria	Some capacity available	Some capacity available	Some capacity available	-KEMRI has some capacity - validations carried out at KEMRI.
	RTKs - HIV	Some capacity available	Some capacity available	Some capacity available	-KEMRI has some capacity - validations carried out at KEMRI.
	PCR kits (COVID-19)	Some capacity available	Some capacity available	Some capacity available	-KEMRI has some capacity - validations carried out at KEMRI.
	Other laboratory diagnostics	TBD	TBD	TBD	
Medical Devices and equipment	Medical Equipment	Some capacity available	Some capacity available	Some capacity available	KEBS has capacity; -PPB has MOU with KEBs on Medical Devices; -Commissioning and installation by supplier also mitigate on quality challenges; -Regulator (PPB) needs to build own capacity
Traditional and herbal medicines	_	Limited	Limited	Limited	
Blood products		YES	YES	YES	-Kenya National Blood Transfusion services
		YES	YES	YES	-Health facilities

Table 3: In-Country quality monitoring capacity for HPT by product category

There is no in-country capacity for testing some HPT especially vaccines, biologicals, and several medical devices, medical equipment, and traditional medicines. Strategic commodities, ARVs, Anti-TBs, Anti-Malarials, FP products and vaccines are extensively tested with significant gaps remaining under essential products. The country capacity is also limited for testing medical equipment and there need to continue building capacity in the Country for testing such equipment.

Role of County Governments in Pre and post market quality monitoring for HPT and mechanisms for engagement

County governments draw their mandate from Article 186 Part II of the Constitution of Kenya 2010 on the roles and functions assigned. Particularly, county Governments have the role of service delivery as stipulated under section 2. County health services, including, in particular— (a) county health facilities and pharmacies. Counties are yet to implement this constitutional function. Secondly, while intergovernmental structures exist for continued engagements on matters of health between the two levels of Government and other Ministry Departments and Agencies (MDAs), however, County Governments, through COG have not been effectively engaged while information sharing has also been limited.

HPT Oversight Bodies	Role
MOH	Policy, Standards, capacity building
Pharmacy and Poisons Board	Regulator; Standards, Enforcement, Pharmacovigilance; Capacity building
National Quality Control Laboratory (NQCL)	Testing; Pharmacovigilance
Mission for Essential Drugs	Procurement and Distribution; Quality Testing; Capacity Building
Kenya Medical Supplies Agency	Procurement and Distribution; Systems strengthening
Kenya Bureau of Standards	Regulation; Standards Enforcement; Quality Testing; Calibration of equipment;
Anti-Counterfeit Agency	Combating substandard and falsified products
Port Health – Kenya Revenue authority	Managing ports of entry – Several Counties lie across the international boarders
Kenya Medical Research Institute	Research; HPT manufacture; Validation of RDTs, RTKs etc.

Table 4: HPT oversight bodies for County Governments engagements on quality of HPT

Recommendations for effective engagement, identification, and management of risks by Counties for better quality of HPT

1. County Governments to remain vigilant especially boarder Counties being vigilant on the boarders that provide risk points for entry of spurious products.
2. County governments to actively pursue the constitutionally assigned role on the oversight of health facilities and pharmacies to ensure that county government quality monitoring activities are well anchored on policy and legislation. Most importantly, is the need to clearly unbundle the pharmacies functions between the two levels of government.
3. County Governments through COG to prioritize active engagements with the HPT oversight institutions tasked with monitoring quality of HPT to facilitate information sharing and use.
4. County Governments, through collaboration with the regulator, to ensure that healthcare workers are sensitized on identification and reporting on substandard and falsified HPT. This should include capacity building on pharmacovigilance within Counties and assigning pharmacovigilance focal persons at Counties and sub-County levels.
5. County Governments to intensify PMS and PV reporting and advocate for expanded scope of Post Market Surveillance to non-prioritized categories especially essential medicines. Counties intensifying pharmacovigilance activities especially through allocation of resources as a supply chain system strengthening component within Counties and strengthening the HPT Units at counties for this role.

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