REPUBLIC OF KENYA

MINISTRY OF HEALTH
DIRECTORATE OF HEALTH PRODUCTS AND TECHNOLOGIES

# SITUATIONAL ANALYSIS REPORT

EVALUATION OF SESSION PAPER NO. 4 OF 2012

ON THE KENYA NATIONAL PHARMACEUTICAL POLICY 2012

NOVEMBER 2023


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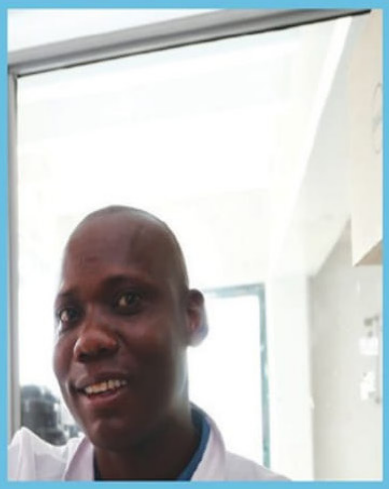

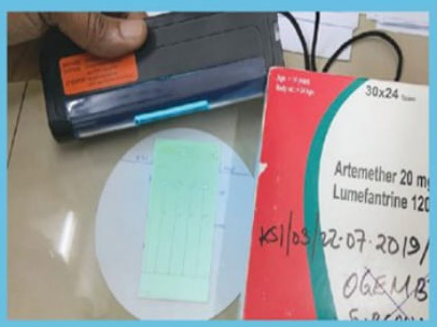
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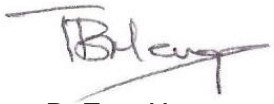
# Acknowledgments

The evaluation of Kenya's National Pharmaceutical Policy, Session Paper No. 4 of 2012, was conducted through a collaborative effort led by a Steering Committee. This committee comprised appointed representatives from the Ministry of Health, Counties, Kenya Medical Supplies Authority, Pharmacy and Poisons Board, tertiary training institutions, National Quality Control Laboratory, Ministry of Investment, Trade and Industrialization, National Referral Hospitals, Kenya Institute for Public Policy Research and Analysis, and Kenya Medical Research Institute.

I want to express sincere gratitude to the dedicated staff of the Directorate of Health Products and Technologies for their exemplary leadership throughout the process. I also extend appreciation to all members of the steering committee who devoted extensive time and effort to the drafting and finalizing this evaluation. Your contributions are invaluable and deeply appreciated.

Furthermore, I would like to offer special thanks to the Africa Resource Centre for their invaluable technical support and for providing the services of a consultant during the evaluation process. Your assistance was instrumental in achieving our objectives.



**Dr Tom Menge**
**Head, Directorate of Health Products and Technologies**
**Ministry of Health**

# Abbreviations and acronyms

| | |
|---|---|
| AGOA | African Growth and Opportunity Act |
| AMA | African Medicines Agency |
| AMR | Antimicrobial Resistance |
| AMU | Appropriate Medicines Use |
| API | Active Pharmaceutical Ingredient |
| ARV | Anti-Retroviral |
| AWaRE | Access, Watch and Reserve |
| BE | Bioequivalence |
| CAP | Chapter |
| CEC | County Executive Committee |
| CECM | County Executive Committee Member |
| CEO | Chief Executive Officer |
| cGMP | Current Good Manufacturing Practice |
| CHAI | Clinton Health Access Initiative |
| CME | Continuous Medical Education |
| COG | Council of Governors |
| COH | Chief Officer of Health |
| COMESA | Common Market for Eastern and Southern Africa |
| CPD | Continuous Professional Development |
| DPS | Director of Pharmaceutical Services |
| DVS | Director of Veterinary Services |
| EAC | East African Community |
| e-LMIS | Electronic Logistics Management Information System |
| EMMS | Essential Medicines and Medical Supplies |
| EMR | Electronic Medical Records |
| EPZ | Export Processing Zone |
| F&Q | Forecasting and Quantification |
| FDA | Food and Drug Authority |
| FIF | Facility Improvement Funds |
| FKPM | Federation of Kenya Pharmaceutical Manufacturers |
| FTAs | Free Trade Agreements |

| | |
|---|---|
| FTC | Federal Trade Commission |
| FY | Financial Year |
| GDP | Good Distribution Practices |
| GMP | Good Manufacturing Practices |
| GSPOA | Global Strategy and Plan of Action |
| HCW | Health Care Worker |
| HISP | Health Insurance Subsidy for the Poor |
| HIV | Human Immunodeficiency Virus |
| HPT | Health Products and Technologies |
| HR | Human Resource |
| ICC | Inter-Agency Coordinating Committee |
| ICT | Information and Communication Technology |
| IFMIS | Integrated Financial Management Information System |
| INN | International Nonproprietary Name |
| IPC | Infection Prevention and Control |
| KEBS | Kenya Bureau of Standards |
| KEDL | Kenya Essential Diagnostic List |
| KEML | Kenya Essential Medicines List |
| KEMRI | Kenya Medical Research Institute |
| KEMSA | Kenya Medical Supplies Authority |
| KEMSL | Kenya Essential Medical Supplies List |
| KFDA | Kenya Food and Drug Authority |
| KHRO | Kenya Health Research Observatory |
| KII | Key Informant Interview |
| KIPI | Kenya Industrial Property Institute |
| KIPPRA | Kenya Institute for Public Policy Research and Analysis |
| KMLTTB | Kenya Medical Laboratory Technicians and Technologists Board |
| KNDP | Kenya National Drug Policy |
| KNPP | Kenya National Pharmaceutical Policy |
| KNQF | Kenya National Qualifications Framework |
| KNRA | Kenya Nuclear Regulatory Authority |
| KPA | Kenya Pharmaceutical Association |
| KRA | Kenya Revenue Authority |
| KTTA | Kenya Tissue and Transplant Authority |
| KU | Kenyatta University |
| LC-MS | Liquid Chromatography - Mass Spectrometry |

| | |
|---|---|
| LMIS | Logistics Management Information System |
| MAPAC | Medicines Affordability and Pricing Advisory Committee |
| MEDS | Mission for Essential Drugs & Supplies |
| MoH | Ministry of Health |
| MOU | Memorandum of Understanding |
| MTC | Medicines and Therapeutics Committee |
| NACADA | National Campaign Against Drug Abuse Authority |
| NACC | National AIDS Control Council |
| NEPAD | New Partnership for Africa's Development |
| NHIF | National Health Insurance Fund |
| NMTC | National Medicines and Therapeutics Committee |
| NQCL | National Quality Control Laboratory |
| NSDCC | National Syndemic Disease Control Council |
| PFMA | Public Finance Management Act |
| PHC | Primary Health Care |
| PMS | Post Marketing Surveillance |
| e-POD | electronic-Proof of Delivery |
| PPB | Pharmacy & Poisons Board |
| PPRA | Public Procurement Regulation Authority |
| PRIMS | Pharmaceutical Regulatory Information Management System |
| PS | Principal Secretary |
| PSK | Pharmaceutical Society of Kenya |
| PV | Pharmacovigilance |
| PvERS | Pharmacovigilance Electronic Reporting System |
| R&D | Research and Development |
| SACU | Southern African Customs Union |
| SEZ | Special Economic Zones |
| SMART | Specific, Measurable, Achievable, Realistic and Timebound. |
| Swap | Sector-Wide Approach |
| TAM | Traditional and Alternative Medicines |
| TRIPS | Trade-Related Aspects of Intellectual Property Rights |
| TTC | Thematic Technical Committees |
| UHC | Universal Health Coverage |
| UN | United Nations |
| VAT | Value Added Tax |
| VMTC | Veterinary Medicines Therapeutic Committee |
| WHO | World Health Organization |

# Executive summary

The government of Kenya promulgated a new constitution in 2010 bringing about significant changes to the health sector, particularly, the devolution of healthcare services and assignment of functions between the two levels of government. Other significant changes impacting the health sector included the equitable sharing of resources between the national government and the county governments, the equalization fund that improves outcomes for the marginalized communities and granting every citizen the right to the highest attainable standard of health and wellness. The Kenya Vision 2030 was launched in 2008 with an aim to make Kenya "a newly-industrializing, middle income country providing a high quality of life to all its citizens in a clean and secure environment". The vision is very strategic on developing key pillars, among them the social, education and economic pillars that have a bearing on the growth of the pharmaceutical sector. It is within the same period that the commencement of the review of the Kenya Drug Policy 1994 began, paving way to the National Pharmaceutical Policy (KNPP) 2012. KNPP 2012 proposed far reaching legal and institutional reforms in the pharma sector, a sector that has a dual role of supporting health service delivery and fostering economic growth through manufacturing. The reforms focused on (i) strengthening leadership and governance to effectively position the sector internationally, regionally, and locally, (ii) restructuring national institutions for the procurement, supply, regulation, and quality control of health products, (iii) building a critical mass of requisite human resources that meet the sector's growth needs, and (iv) consolidating a strong partnership and collaboration among the actors. The overall goal was to achieve universal access to Essential Health Products and Technologies.

The implementation of KNPP, among other critical government policies, has remained paramount in building a progressive, responsive, and sustainable health-care system that is responsive to routine healthcare needs and emergencies. During the implementation period, other key sector milestones were realized such as the development of the Kenya health Policy 2014-2030, the enactment of the Health Act 2017, the prioritization of Universal Health Coverage that saw an array of legislations, policies, strategies & guidelines developed among them, the UHC Policy 2020-2030. The outbreak of COVID 19 too, had overarching yet negative effects on health, the global value chains and staggering devastation on the economy thereby necessitating governments to rethink self-reliance and sustainability. This gave further impetus to local production of HPT, an additional, yet much needed attention for the pharmaceutical sector. For example, with the need to locally manufacture vaccines and other HPT, efforts to achieve World Health Organization (WHO) Maturity level 3 status for the Pharmacy and Poisons Board saw some of the overlooked KNPP strategic actions not only implemented but fast tracked. Indeed, throughout these processes, HPT received varying degrees of attention that impacted how the policy got implemented or not.

The evaluation of NPP Sessional Paper No. 4 of 2012 covered the period ending December 2022. The goal of the evaluation was to determine the extent to which the policy was implemented, learn about what worked or did not work, what contributed to policy success or failure and subsequently inform decisions on whether and how the policy needs to change. Specifically, the policy evaluation was process oriented and aimed at evaluating the relevance, effectiveness, and the utility of the policy, inform the review and generate recommendations to guide the development of new policy.

# Methodology

A steering committee was appointed by the Director General for Health. With the support of a consultant, the evaluation process began with the Division of HPT providing the requisite leadership and secretarial role. Data collection was done through two phases comprising a desk review and key informant interviews. Through desk reviews, the implementation status of interventions for each of the twelve (12) KNPP pillars was scored based on the number of interventions implemented, ongoing or not implemented, against the total number of interventions outlined. Key informant interviews were conducted to collaborate information from the desk review. The steering committee and the secretariat were critical in peer reviewing and validating the reports.

## General findings

1. KNPP 2012 envisioned having a well-governed pharmaceutical sector that would promote access to essential medicines and health technologies to all Kenyans and contribute to social and economic development. The vision was forward looking and still applicable in 2023, eleven years later.

2. Though the policy recognizes HPT to encompass those products intended for use or application in the attainment of health, it stated that pharmaceuticals were the core HPT and assumed that principles and norms applicable to the pharmaceutical sector would be equally adaptable to other HPT. The review revealed that other product category stakeholders did not, to a large extent, identify with the policy.

3. KNPP was non-self-executing, requiring several key legislations to be made for its effective implementation. Among them was the establishment of the "Kenya Drug Authority" or rather, a single regulatory body for all HPT, undertaking critical processes to confer functional and financial autonomy to key HPT national institutions such as the 'KDA'/PPB, the NQCL, KEMSA etc. as well as a pharmacy council for the regulation of pharmaceutical practice. With only KEMSA becoming an Authority in 2013, all other institutions autonomy remained unachieved at the end of the policy implementation period.

4. While KNPP 2012 and the Health Act 2017 demonstrate coherence in reducing fragmentation through consolidation and the establishment of a single regulatory body for the regulation of all HPT, this is not the case in practice at the time of the review as there were ongoing processes on establishment of institutions such as KNRA, KTTA, etc. that have the same mandate for regulation of HPT.

5. KNPP was set to be implemented in two five-year strategic plans over the 10-year period; this did not happen and only one inaugural HPT Supply Chain Strategic Plan was developed towards the end of its life cycle in 2020 significantly impacting implementation.

6. In strengthening leadership and governance, there was proposed a Director of Pharmaceutical Services at the level of the Director of Medical Services. However, for the first seven (7) years of the policy implementation, between 2013 and 2019, the pharmacy department was scrapped of the official MOH organogram existing as a Unit and later in 2019, a division of HPT was created at a lower level. This is likely to have affected how the policy was envisioned to be implemented.

7. KNPP 2012 lacked a monitoring and implementation plan that would provide a clear performance metric against which performance could be monitored, evaluated, and reported. KNPP 2012 was not costed. A midterm evaluation that would have remedied some of the challenges was also not conducted.

8. Some components of the KNPP have been implemented albeit difficult to directly link back to the policy.

9. Some of the policy interventions were not SMART for implementation. Words like 'encourage' depict a good thing to do, do not demonstrate an authoritative decision by the government on what should be done or what should not be done.

# Specific findings

The implementation rate of interventions by pillar ranges between zero (0) and one (1) and details are as summarized below with activities fully achieved scored 1, those in progress or not fully achieved, 0.5 and those not done, 0

**Pillar 1: Revamping pharmaceutical sector governance and policy direction** had an implementation rate of 17%, with none of the interventions being fully implemented. This is a critical pillar that set out to strengthen governance including the establishment of the Director of Pharmaceutical Services.

**Pillar 2: Strengthening pharmaceutical sector regulation at 29%.** While some aspects of registration of HPT are in good progress, other aspects including HPT scheduling as envisioned are yet to be achieved.

**Pillar 3: Expanding availability of essential medicines** with an implementation rate of 50%. Some of the implemented interventions include restructuring KEMSA, and putting in place an effective, integrated and optimized public sector procuring system and enforcement of good distribution practices. However, a lot is required to enhance public private collaboration and pooled procurement at institutional and regional levels.

**Pillar 4: Expanding local pharmaceutical production** having 30% implementation. There is slow progress in this critical area, and little has been done to encourage technology transfer.

**Pillar 5: Improving affordability of essential medicines** scored 47%. Subsidized HPT at primary level and exemption mechanisms have fostered affordability. However, there are no mechanisms for HPT pricing transparency, price monitoring and enforcement of generic prescription among other interventions to ensure affordability.

**Pillar 6: Promoting appropriate medicines use** with 50% implementation rate. The pillar focused on the MTCs at both national and counties, review of HPT lists, promotion of essential medicines concept, monitoring of therapeutic trends, regulation of HPT promotion, appropriate medicines use and consumer feedback mechanisms including in TAM. These have been done to some extent but still present great opportunity in enhancing clinical governance in the use of HPT.

**Pillar 7: Pharmaceutical Research and development use** with 58% implementation rate. Despite showing good progress, it was noted that there is no good coordination for pharmaceutical services research.

**Pillar 8: Information and communication technology (ICT)** scored 67% and sought to ensure effective investment in ICT infrastructure for pharmaceutical systems, and the regulation of online pharmacy.

**Pillar 9: Human resources for the pharmaceutical sector** with a high score of 70%. This encompassed the expansion of training capacities and increased variety, and scope of post graduate courses, career progression, recruitment of recruitment of pharmaceutical personnel and review of the schemes of services

for pharmaceutical personnel among others. Despite this, there was lack of recognition for pharmaceutical specializations nor mechanisms to enable mutual recognition of pharmaceutical personnel in the context of regional integration and international cooperation.

**Pillar 10: Promoting access and safeguarding public health in pharmaceutical trade** at 13% with only one intervention fully done. Scoring the least, the pillar envisioned building capacity to negotiate, safeguard TRIPS and endow negotiators at bilateral and multilateral levels with necessary negotiation skills and facilitating Kenya's participation in regional and international initiatives. It was noted that although Kenya is a signatory to regional and global initiatives there is limited evidence on the extent to which the country is benefiting from the initiatives.

**Pillar 11: Enhancing access to veterinary medicines could not be evaluated as** all Veterinary products are regulated under the Kenya Veterinary Board in 2015 in the Ministry of Agriculture and Livestock. Particularly, this sought to enhance structures and foster collaboration, have all veterinary medicines registered by the FDA as well as establish Veterinary Medicines and Therapeutic Committee (VMTC). The aspirations are still valid at a time the Country is battling antimicrobial resistance among other concerns that would benefit from strengthened collaborations and harmonized regulatory systems.

**Pillar 12: Financing for essential pharmaceuticals and pharmaceutical services** scored 64% and indicates good progress. Envisioned in this pillar was a clear definition of financing mechanisms for HPT, mobilization, and allocation of adequate financial resources as well as ring fencing resources. The costed HPT supply chain strategy, forecasting and quantification of national HPT needs, continued ascent to county FIF Bills, abolishment of user fees and waivers in health facilities and ongoing health sector financing reforms put this indicator on good trajectory.

The development of a new policy will take into consideration the successes and challenges identified and most importantly, have a holistic approach to all HPT.

# 2. Introduction

## 2.1. Background

The need to reform the pharmaceutical sector led to the development of the Kenya National Drug Policy (KNDP) of 1994. The implementation of KNDP of 1994 was however hampered by requisite legal, administrative and financial support. The Kenya National Pharmaceutical Policy (KNPP) Sessional Paper No. 4 of 2012 succeeded the KNDP of 1994. The KNDP was in place for twelve (12) years prior to commencement of its review of KNPP in 2006 and was replaced after eighteen 18 years upon accent of KNPP as Sessional Paper No. 4 of 2012.

The KNPP 2012 provides overarching policy direction through twelve interlinked pillars with each pillar having a background, institutional and legal arrangement, challenges, and proposed interventions.

The 12 pillars are:

Pillar I: Revamping pharmaceutical sector governance and policy direction

Pillar 2: Strengthen pharmaceutical regulation of products and services.

Pillar 3: Expanding availability of essential medicines.

Pillar 4: Expanding local pharmaceutical production.

Pillar 5: Improving affordability of essential medicines.

Pillar 6: Promoting appropriate use of medicines including traditional medicines.

Pillar 7: Promotion of research and innovation in medicines to address priority health issues.

Pillar 8: Embrace Information and Communication Technology (ICT) in all aspects of pharmacy.

Pillar 9: Human resource development for delivery of pharmaceutical services

Pillar 10: Promote access and safeguarding health in pharmaceutical trade.

Pillar 11 Enhance access to veterinary medicine.

Pillar 12: Mobilize and appropriately allocate financial resources for equitable provision of pharmaceutical services.

KNPP 2012 envisioned having a well-governed pharmaceutical sector that would promote access to essential medicines and health technologies to all Kenyans and contribute to social and economic development. The intention for the KNPP 2012 was to address the pharmaceutical sector and assumed that (i) principles and norms applicable to the pharmaceutical sector would equally be adaptable to other Health Products and Technologies (HPT); (ii) the critical pharmaceutical sector issues also cut across all the health systems building blocks and (iii) availability of robust implementation structures (iv) dynamism and flexibility may prevail including in periods of emergencies as observed with COVID-19, changes brought about by decentralization of governance structures and emerging sector needs.

## 2.2. Overview of public policy

Public policy is a purposive and consistent course of action produced and pursued by the government as a response to a perceived problem of a sector, constituency, formulated by a specific political process, and adopted, implemented, and enforced by a public agency. Public policy can further be described as a statement of government commitment, which articulates basic principles to be pursued to attain specific goals and actions.

The policy making cycle has six stages: (1) problem identification; (2) agenda-setting; (3) policy design; (4) approval; (5) implementation; and (6) monitoring and evaluation. Policy making covers the first four steps. Implementation entails planning to design and develop objectives, outcomes and measures and action plans clearly spelling out responsibilities. The final step entails documenting progress of action plan implementation and finally evaluation at end of policy to inform policy review where applicable.

Development of public policies take different, and often sequential, forms as they move along the approval process as described in Figure 1.

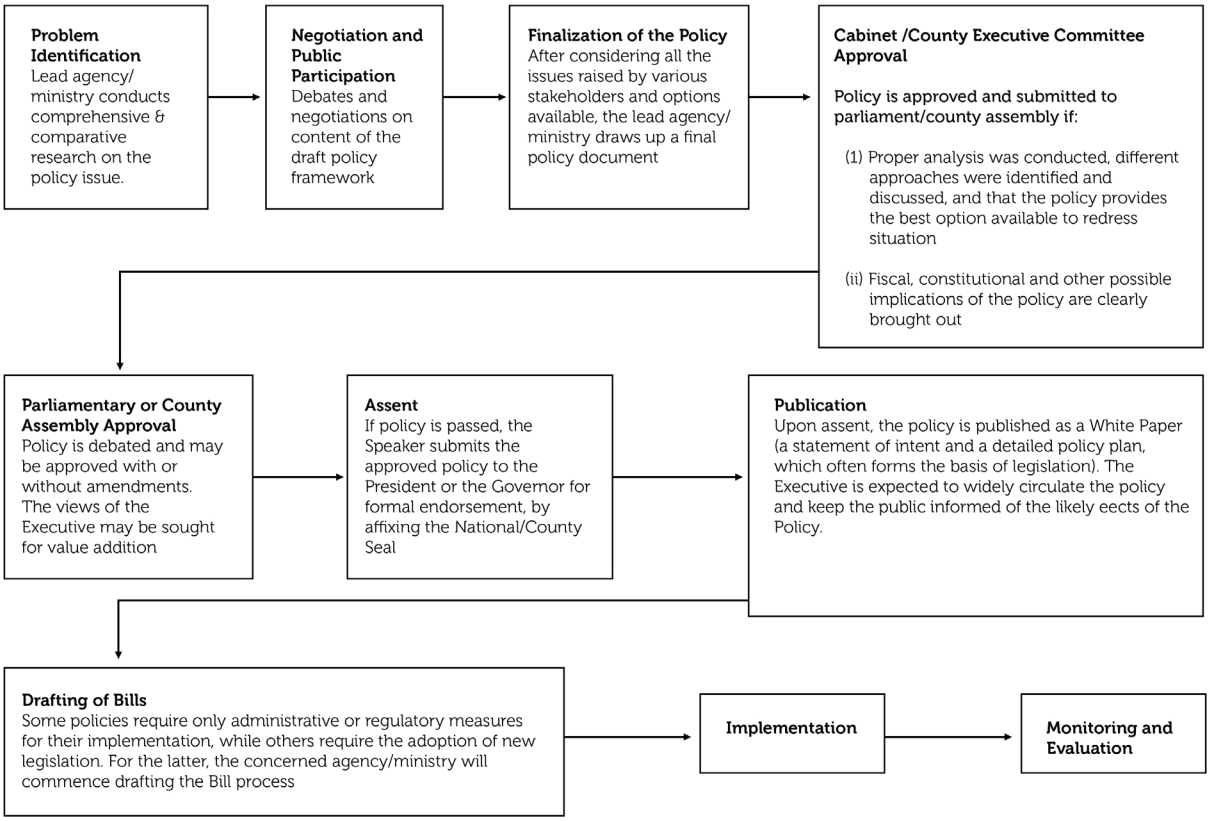



*Figure 1: Public Policy making process. [Source: KIPPRA]*

Public policies can transition from Policy Brief to Green Paper (Technical Issues Paper), County Executive Committee (CEC) Memorandum or Cabinet Memo and White Paper (Sessional Paper). Once problems have been identified and appropriate context and baseline established, a policy brief is generated. This is followed by policy formulation where options are explored and evaluated, and policy objectives and outcomes laid out. At this stage, policy measures that require law, regulation or administrative action

are identified and lead to generation of a green paper (technical issues paper). The final phase involves consolidation and translation of policy proposals for approval, through cabinet Memo for the County Executive Committee or cabinet and the Sessional Paper for the County Assembly or parliament. The decision to develop new legislation (law and regulation) depends on: (i) whether the given policy is self-executing; (ii) the cost-benefit analysis of the proposal; (iii) the existence of similar applicable law and consistency with the constitutional framework; and (iv) whether the issue can only be resolved by way of other legislative initiatives. A self-executing policy only requires administrative action such as executive orders, circulars and guidelines and is immediately implementable while a non-self-executing policy requires further development/passage of laws and/or regulations to facilitate its implementation. The ideal and recommended position in the legislative process is for policy to precede formulation of a legislative instrument e.g., Bill. The rationale for first developing a policy framework is to assess the problem and possible solutions, and define the opportunity to be embraced and the modalities or approaches to realize the benefit prior to proposing the necessary legal framework.

## 2.3. Rationale for KNPP 2012 evaluation

Evaluation is the systematic process that helps to determine if the implementation of a policy was closely monitored, whether any outcomes and impacts are evident and its relevance, efficiency, and effectiveness. Public policy is operationalized through implementation of outlined interventions and development and adoption of laws, rules, or regulations where necessary. Policy evaluation is therefore critical to determine what the consequences of public policy are and what has and has not been achieved. Policy evaluation helps get judgments about quality, goal achievement, implementation effectiveness, impact, and whether costs can be determined.

KNPP 2012 came into play after Kenyans enacted a new constitution in 2010 that established a system of devolved government, but just a year prior to its adoption in 2013. Its alignment to the devolved structure has therefore not been evaluated and/or aligned. Additionally, key overarching documents on devolution, global and country health goals have been developed such as, Public Finance Management Act (2012), Transition to Devolved Government Act (2013), Health Act (2017), Health Policy (2014-2030) and Universal Health Coverage (UHC) Policy 2020-2030 among others that may affect the KNPP and are in place. Evaluation of the policy was therefore fundamental to determine whether the content clearly articulated the goals of the policy, its implementation and the underlying logic for why the policy will produce intended change and whether the policy was implemented as intended and its effectiveness.

## 2.4. Goal and objectives

The goal of the KNPP evaluation was to determine to what extent the policy was implemented, learn about what worked or did not work, what contributed to policy success or failure and subsequently inform decisions on whether and how the policy needs to change.

Specifically, the policy evaluation was process oriented and aimed to review its:

1. Relevance - to what extent were the policy scope, principles and objectives pertinent in relation to the evolving needs and priorities of government. Are there issues that persist and therefore need to be addressed?

2. Effectiveness – to what extent was the policy implemented.

3. Utility - how do the results of the policy compare with the needs of the target audience(s).

4. Inform review-generate recommendations to guide review of the policy/development of new policy.

# 3. Methodology

The policy evaluation entailed the following process.

1. Planning
2. Data collection through desk review and key informant interviews
3. Data analysis and report compilation
4. Peer review and validation of report

## 3.1. Planning phase

This phase entailed the development of terms of reference (TOR) for the steering committee and consultants by the division of Health Products and Technologies (DHPT) secretariat. Steering committee members were identified and appointed by the Director General for Health. Consultant was recruited with support from an implementing partner.

## 3.2. Data collection

Data collection was done through two phases: desk review and key informant interviews.

### 3.2.1. Desk review

The first phase of the evaluation comprised compilation of documents relevant to KNPP evaluation per pillar. To establish a relationship with KNPP, a check to understand why the documents were produced was done. Desk review of the relevant documentation included Acts of Parliament, policy documents of government ministries, departments, and agencies, published reports, available reviews & assessments related to KNPP to determine and demonstrate evidence of what has been accomplished within each pillar and the gaps and challenges that may have been experienced in its implementation. Documentation from local, regional, and international health bodies including various United Nations (UN) organizations, World Health Organization, NEPAD, East Africa Community and the African Union and countries that have established pharmaceutical policies such as the United Kingdom, Australia, The European Union and South Africa were also reviewed.

Documentation of information on what has been achieved, what is being done and what has yet to be done for each pillar was done using a standard tool. Implementation status of interventions for each pillar was scored where the score was calculated based on the number of interventions implemented or ongoing against the total number of interventions outlined in KNPP. Details of status were summarized and recommendations for consideration during policy review were provided.

## 3.3. Key informant interviews

In the second phase of the evaluation, key informant interviews (KII) were done and entailed conversation with people presumed to be knowledgeable on KNPP and potential implementers or facilitators of implementation. Related pillars among the twelve (12) were categorized into six (6) thematic areas. Stakeholders' mapping was done for each pillar and key informants identified for each thematic area.

A standard tool with general questions and specific questions per pillar was developed and used for the interviews. Interviews were carried out through online or physical meetings. Documentation of conversation was done through consented recording and transcription. Interviews were carried out by members of the steering committee with support from the secretariat team. Relevant information that was additive or augmentative to the desk review findings was extracted thematically by identifying clusters of comments per pillar.

## 3.4. Peer review and validation of report

The desk review and key informant reports were separately reviewed by the secretariat. The consolidated report was reviewed by the steering committee. Feedback from the reviews was discussed for alignment and consensus and incorporated in the report. The final report was validated by the secretariat.

## 3.5. Limitations

Information collected through the desk review was affected by availability of published content and key informant interviews might be missing details, components or underreporting the specific issues. Completeness of information may be varying depending on document reviewed and stakeholders interviewed.

# 4. Findings

A formative policy evaluation (process evaluation) was done and focused on establishing implementation status of the policy, prevailing contextual factors, processes, and mechanisms that underpin a policy's success or failure, and why.

**Summary of key findings**

1. KNPP 2012 envisioned having a well-governed pharmaceutical sector that would promote access to essential medicines and health technologies to all Kenyans and contribute to social and economic development. The vision was forward looking and still applicable in 2023, eleven years later.

2. Though the policy recognizes HPT to encompass those products intended for use or application in the attainment of health, it stated that pharmaceuticals were the core HPT and assumed that principles and norms applicable to the pharmaceutical sector would be equally adaptable to other HPT.

3. There was no implementation framework or plan that would have been used to guide implementation and lobby for fund allocations in support of implementation. However, some components have been implemented though albeit difficult to directly link back to the policy. The office of the chief pharmacist that was in place at the time of the policy publication was dismantled over time to create small units before formation of Division of health products and technologies in 2018 and then elevation to directorate in 2023.

4. Some of the policy interventions were not SMART for implementation. Words like 'encourage' depict a good thing to do and do not demonstrate an authoritative decision by the government on what should be done or what should not be done.

5. Reference to Food and Drug Authority (FDA) as the regulatory authority was misaligned as the same policy proposed its set-up and went ahead to assume that it exists and refer to it in all areas where the responsibility was for the regulator. It would have been appropriate to be generic and refer to regulatory authority rather than being specific to FDA.

6. Implementation rate of interventions by pillar ranges between zero (0) and one (1) and details are as summarized in the table below. Activities fully achieved were scored 1, those in progress or not fully achieved, 0.5 and those not done, 0.

## Table 1: KNPP interventions and level of implementation per pillar

| Interventions | Remarks |
|---|---|
| **Pillar 1: Revamping pharmaceutical sector governance and policy direction.**<br><br>**Observations:** Five out of six interventions were higher priority issue and well structured<br><br>**Implementation rate:** 17%, None of the interventions were fully implemented, two were in progress of implementation and 4 had not been implemented. | |
| i. Establishing a Directorate of Pharmaceutical Services (DPS), or its equivalent, | **Not done.** Pre-devolution (before 2013), the department of pharmacy was at level 4 of the MoH organogram from the Minister level. Post devolution, the department of Pharmacy was disposed of and remained non-existent in the Ministry of Health organogram for a period of 7 years between 2013-2019 and existed as a unit with no staffing capacity. This significantly affected the dissemination and implementation of the KNPP which was envisioned to be implemented in a two -5-year strategic plan over its ten-year period. In 2019, the division of Health Products and Technologies (DHPT) was established which was at level 6 of the MoH organogram from the Minister level. Plans were underway to elevate the division to a directorate which will take it back to level 4 of the MoH organogram from the Minister level. |
| ii. Review of schemes of service for pharmaceutical personnel to recognize specialization | **Not Done.** Recognition of specialization has not been done. Schemes of Service for both Pharmacists and Pharmaceutical Technologists were both reviewed and approved by the Public Service Commission in September 2016 but did not recognize specializations. It is observed that the Scheme of Service job grades as provided by Public Service Commission across cadres to effect appropriate deployment and career progression but does not specifically recognize specialties, which is a function of/ requires to be done by the regulator. However, draft Guidelines on Recognition of Pharmacy Specialties by Pharmacy and Poisons Board (PPB) are in place. There are no regulations incorporated in CAP 244 for recognition of specializations in Pharmacy. |
| iii. Encourage the development of the requisite human resource capacity to address current and emerging pharmaceutical and health sector needs. | **In progress.** This intervention was not SMART. The Status of Healthcare Professionals in Kenya assessment of 2015 showed that there was an increase in training outputs and productions of health workers in the country across medical cadres analyzed (nurses, clinical officers, medical doctors, dentists, laboratory technologists and technicians) except for pharmacists. A Labour Market Analysis in Kenya in 2022 to generate evidence on the relationship between supply, demand and need of the health labour force indicated that the stock of pharmacists and pharmaceutical technologists increased by 129% from 6776 to 15 498, between 2010 and 2020. The training institutions have increased the scope of specialization courses being offered e.g. industrial pharmacy. However, developing human capacity for personnel in the pharmaceutical industry especially in product development and design, manufacturing using advanced technology remains a gap. There is also need to ensure pre-service institutions are aligned to the market needs and therefore an assessment in these areas is required to guide the next policy review |
| iv. Restructure the PPB to establish a Food and Drug Authority (FDA) as an autonomous national regulatory agency within the ministry responsible for health, and delinked from the directorate of medical services | **Not done.** FDA was not formed. PPB has inadequate autonomy to undertake its functions. Although established as a body corporate since 1993, it continues to operate as a department within the Ministry of Health. Most technical staff are seconded from MoH and the Board has no control over their deployment to and from the Board. The HPT bill is underway to establish a single regulatory authority for all HPT. |
| v. Restructuring of Kenya Medical Supplies Agency (KEMSA) as an autonomous body corporate though established through an Act of parliament | **In progress.** The change from an agency to an authority was affected in 2013 through the Kenya Medical Supplies Authority Act. The Act gave KEMSA autonomy to run its core mandate of procurement, warehousing, and distribution. However, KEMSA has not fully achieved operational and financial autonomy |

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| vi. Restructure the National Quality Control Laboratory (NQCL) as an autonomous body corporate within the ministry responsible for health, delinked from the drug regulatory authority. | **Not done.** NQCL Board is appointed by PPB and its staff are posted by the Ministry of Health and thus not autonomous. |
| **Pillar 2: Strengthening pharmaceutical sector regulation.**<br><br>**Observations:** This pillar had eleven interventions. However, intervention no. 6 was separated during the evaluation as it had two interventions that required to be evaluated separately.<br><br>**Implementation rate:** 29%, One intervention was fully implemented, five were in progress of implementation and six had not been implemented. | |
| i. All products marketed in Kenya must be duly registered by the FDA. | **In progress.** This intervention has not been fully achieved. Surveys have revealed that there are medicines not registered and other HPT not listed by the regulator. In a rapid result initiative of Post Market Surveillance (PMS) done in 2019, it was revealed that 14% of sampled products were not registered by the national regulator. Examples-syringes- 53.6%; male condoms-35.3%; folic acid-44%; amoxicillin-9.4%, albendazole-7.7%, etc.). There is also progress in the same front where some of the programs have enjoyed intensive PMS monitoring including Antiretroviral (ARVs), AntiTB , Antimalaria and Family planning HPT. The Global Fund supported Malaria PMS round 1-7 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. The FDA has not been established. |
| ii. A scheduling system for medicines will be reviewed, regularly updated, and enforced. The schedule will delineate appropriate levels of control for medicines prescribing, dispensing and use, based on their pharmacological and safety profile. | **Not done.** Scheduling has not been done. Guidelines for scheduling of HPT version 1 of 2022 were in place. African Union model law on scheduling has been adopted in the guidelines and included in the proposed HPT bill. The bill also proposes a scheduling committee to be reviewing and updating the schedules on regular basis |
| iii. Registered products will require renewal of registration every 5 years, based on defined criteria. The FDA may de-register products that fail to conform to the set requirements. | **Not done.** As provided in the Cap 244, registration of medicines is done once and retention done annually. Other HPT are listed and not registered by PPB. The FDA has not been established |
| iv. Premises where medicines are stored, distributed and dispensed must be licensed | **In progress.** This intervention has not been fully achieved as there are reports of regular crackdowns on unlicensed pharmacies. |
| v. Only personnel registered or enrolled by the Pharmacy Council will be authorized to manage and dispense medicines. To enhance professional regulation, all pharmaceutical personnel will be required to maintain current membership of their professional association. | **Not done.** The interventions envisioned that medicines would be handled by registered/enrolled pharmaceutical professionals. However, this has not been achieved by both the private and public sector. Through crackdowns by the regulator (PPB), it has been revealed that there are unregistered/enrolled persons in the private sector. In the public sector, due to task shifting especially in the primary health facilities (dispensaries, health centers and community) management and dispensing of medicines is done by non-pharmaceutical personnel. Being a member of a professional association is voluntary and has no relationship with registration/enrollment. The envisioned pharmacy council has not been established |

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| vi. a) All pharmaceutical inspectorate functions will be consolidated and strengthened under the FDA. | **Not done.** This intervention had two components. The first component envisioned consolidation of regulation on inspection under FDA. This intervention has not been achieved as the FDA has not been put in place. There are many regulatory bodies that carry out inspections on HPT e.g. KMLTTB, KEBS, Public health Kenya Nuclear Regulatory Authority (KNRA) etc. |
| b) Only inspectors designated by the FDA will be authorized to inspect pharmaceutical products and premises. | **Not done.** Component 2 on the profession of inspectors, trained inspectors for medicines were in place from 2003. However, inspectors for other HPT e.g., diagnostics, nutrition, medical devices were not in place. |
| vii. Clinical trials and other research activities involving the administration of medicines under research to human subjects will be regulated by the FDA. | **Done.** Progress has been made in incorporating clinical trials into Cap 244 in the 2022 amendments. Guidelines on clinical trials were developed in 2022. Available evidence shows that by 2020, 60% of clinical trials had been registered and monitored with 50% having been compliant with the clinical guidelines (PPB strategic plan 2020-2025). |
| viii. Cosmetics and other pharmacologically relevant chemicals and devices will be subject to regulation by the FDA. | **In progress.** In Cap 244 2012 amendments, cosmetics were defined as substance or mixture of substances manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair, eyes or teeth, and includes deodorants and perfumes. Cosmetics were included as health products in the Cap 244 2022 amendments. Through inclusion of cosmetics as health products and devices as health technologies, regulations for all HPT apply across. On cosmetics, the first edition of the General requirements for Safety of Cosmetic Products was published by KEBS in 2021. Despite Cap 244 providing for regulation of cosmetics, this seems not to have been advanced by PPB. By 2020, no dietary and cosmetics had been evaluated by PPB. In the 2020-2025 PPB strategic plan, the PPB planned to develop guidelines on cosmetics but this had not been done by end 2022. Guidelines for registration of medical devices including in-vitro diagnostics were published in 2022. |
| ix. All pharmaceuticals for veterinary use will be subject to regulation by the FDA. | **Not done.** This intervention envisioned regulation consolidation for all human and animal products under one body i.e. FDA. However, the FDA was not established and Veterinary products remain under the Veterinary Products Regulations 2011 |
| x. The FDA will collaborate with other regulators, and law enforcement agencies; and participate in harmonization, reciprocal arrangements and other initiatives for enhancing pharmaceutical regulation and control. | **In progress.** This intervention was not clear in terms of whether the collaboration was with other regulators locally and/or regional and global level. However, the regulator (PPB) has collaborated with other local regulators such as KEBS on cosmetics regulations, police forces for enforcements; there has been efforts for standardization of regulations in for the COMESA countries and PPB in the process of acquiring global standards i.e. World Health Organization (WHO) level 3 maturity status |
| xi. a) Effective mechanisms will be established to address conflict of interest in pharmaceutical regulatory decision-making, and<br><br>b) for the handling of complaints, disputes and disciplinary matters arising from pharmaceutical regulation and practice. | **Done.** Prior to establishment of the office of the Chief Executive Officer (CEO) at PPB in 2019, the chief pharmacist was in-charge of policy at MoH and was the registrar for PPB. This was a conflict of functions. Separation of the function has been done.<br><br>**Done.** PPB have a disciplinary mechanism in place. |

| **Pillar 3: Expanding availability of essential medicines**<br><br>**Observations:** This pillar had ten interventions.<br><br>**Implementation rate:** 50%. Three interventions were fully implemented, four were in progress and three were not implemented. | |
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| i. Integrate and harmonize existing public sector parallel procurement activities to optimize procurement efficiency and effectiveness. | **In progress.** Prior to the roll-out of devolution the KEMSA had the statutory mandate for procurement, warehousing and distribution of all health products to all government health facilities. However, facilities often reported prolonged delays in servicing their orders by KEMSA, and very low refill rates, leading to long periods of stock out. As a result, counties resulted to alternative sourcing. This option led to product quality concerns, lack of benefits of economies of scale among other inefficiencies. Post devolution of health services, the implementation of this intervention proved complex due to the independence of the county governments. To try and address the challenge, amendments were made to the KEMSA Act in 2019 to have all counties procure from KEMSA and made it an offense not to procure from KEMSA. Challenges of low order fill rates have persisted and there is a bill (2021) to amend to have counties source health products from alternative sources. The KEMSA bill 2021 seeks to delete the legal provisions that require the county governments to procure from KEMSA. |
| ii. Develop an effective system for the procurement and supply of essential pharmaceuticals for disasters and emergencies. | **In progress.** An emergency supply chain framework was developed and signed in 2021. A consolidated system for procurement and sourcing of health products was lacking. During emergencies, products are sourced from KEMSA and support is also sourced from partners. Due to lack of the emergency supply chain preparedness and response system, procurement inefficiencies were reported as well as push of products that lead to stockpiling of unwanted products during Covid19 outbreak. However, systems for expedited review and authorization of products during emergencies are in place with the PPB. |
| iii. Encourage specialization in pharmaceutical procurement and logistics, through relevant training, deployment and retention measures. | **In progress.** This intervention was not SMART. Guideline for Pharmacy Specialists developed, number of pharmaceutical procurement and logistics specialists has increased. MoH sponsorships for specialization in health products supply chain management ongoing. KEMSA also sponsors training of staff on procurement along with other relevant certifications |
| iv. Through the FDA, establish standards for, and enforce compliance with Good Distribution Practices (GDP), including pharmaceutical logistics infrastructure at all stages of the pharmaceutical supply chain. | **In progress.** Guidelines on good distribution practice and transportation were developed in 2022 are in place. However, compliance with the guidelines has not been established (PPB strategic plan 2020-2025). |
| v. Ensure that public procurement of medicines for veterinary use follows the same principles outlined in this policy. | **Not done.** Through the formation of the FDA, it was envisioned that all human and animal health products would be integrated. However, FDA was not formed and therefore this intervention was not achieved as veterinary medicines are managed separately |

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| vi. Restructure KEMSA by statute, as the centralized, autonomous, primary public procurement agency for integrated public-sector procurement and supply of medicines, medical supplies, medical devices and equipment. | **Done.** This intervention is related to no. 1. KEMSA was established as an authority by Act of parliament in 2013 with a core mandate to procure, warehouse and distribute drugs and medical supplies to the public health facilities. Prior to the roll-out of devolution the KEMSA had the statutory mandate for procurement, warehousing and distribution of all health products to all government health facilities. However, facilities often reported prolonged delays in servicing their orders by KEMSA, and very low refill rates, leading to long periods of stock out. As a result, counties resulted in alternative sourcing. This option led to product quality concerns, lack of benefits of economies of scale among other inefficiencies. Post devolution of health services, the implementation of this intervention proved complex due to the independence of the county governments. To try address the challenge amendments were made to the KEMSA Act in 2019 to have all counties procure from KEMSA and made it an offense not to procure from KEMSA. Challenges of low order fill rates have persisted and there is a bill (2021) to amend to have counties source health products from alternative sources. The KEMSA bill 2021 seeks to delete the legal provisions that require the county governments to procure from KEMSA. |
| vii. Coordinate procurement of Essential Medicines and Medical Supplies (EMMS) in the context of Sector Wide Approach (SWAp) through the Procurement Interagency Coordinating Committee (P-ICC). | **In progress.** Interagency coordinating committee for health products has been in place with members appointed as per the TORs as guided by the Kenya Health sector coordination framework 2018-2030. The ICC is not specific to procurement and discusses all matters HPT. However, the committee has not been meeting consistently. |
| viii. Encourage collaboration between public and non-public procuring entities for EMMS, including pooled procurement at institutional and sub-regional levels. | **Not done.** This intervention was not SMART. This intervention has not been implemented. However, draft guidelines on Pooled Procurement of low demand and high cost HPT are in place |
| ix. Encourage and facilitate outsourcing or privatization of non-core functions in public pharmaceutical procurement and supply. | **Done.** This intervention was not SMART. Transport and logistics are outsourced by KEMSA. KEMSA has a framework for outsourced distribution |
| x. Develop and gazette zoning regulations to promote equitable access to pharmaceutical products and services in the establishment of wholesale and retail pharmaceutical outlets. | **Not done.** This intervention has not been implemented. Guidelines for registration and licensing of premises under development in 2022 provided for a consideration of reasonable distance be maintained between any two registered premises to discourage unfair competitive trade practices. However, it had not been enforced. |

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| **Pillar 4:** Expanding local pharmaceutical production.<br><br>**Observations:** This pillar had six interventions. Intervention one had two unrelated and they were separated for objective evaluation. Intervention 5 and 6 were not evaluated as there were similar interventions in other pillars Intervention 5 was covered under Pillar 3, interventions 1, 2, 6 and 7 while intervention 6 was covered under intervention 1 in this pillar.<br><br>**Implementation rate:** 30%. Three interventions were in progress while two were not done | |
| i. a) Create an enabling environment to encourage investment in local production of quality essential medicines. | **In progress.** Cost of registering and retaining locally manufactured health products is lower than those imported. An assessment was done in 2020/2021 to establish status of local manufacture of HPT and provide guidance on improving availability of established quality and affordable essential HPT through promotion of local production. The assessment led to identification of products for consideration in the preferential procurement in line with the buy Kenya build Kenya initiative. Efforts to advance local manufacturing of health products have been in place through task forces by NACC and MoH. Kenya's Export Processing Zones (EPZ) and Special Economic Zones (SEZ) offer special incentives for manufacturing firms operating within Kenya. There is continuous engagement with the national treasury for a favourable tax regime for local manufacturers. However stiff competitions from uncontrolled importation remain a major challenge. |
| b) Compliance with established standards for current Good Manufacturing Practice (cGMP). | **In progress.** There exists GMP guidelines and PPB enforces them through inspections of manufacturing sites. However, various assessments have revealed that not all manufacturers in Kenya comply with the GMP. In an assessment by Vugigi et al (2019) showed that GMP standard varied among the facilities in the Kenyan pharmaceutical industry, nine of the 16 pharmaceutical manufacturers assessed complied with GMP standard in regard to manufacturing premises. |
| ii. Encourage technology transfer and international accreditation of local manufacturers to enhance their competitiveness. | **Not done.** PPB in their strategic plan 2020-2025 planned to develop guidelines for technology transfer of registration of new and high technology medicines, however, this has not been developed by the end of 2022. The Kenya Pharmaceutical Industry diagnostics report revealed that the Kenyan pharmaceutical sector has not yet moved towards the most complex activities of the value chain and most companies manufacture simple non-patented products or rely on technology transfer agreements with foreign multinational manufacturers. A study by Mwangi, J.M (2015) assessing the viability of pharmaceutical technology transfer in Kenya indicated that only 48.6% (n=17) of the respondent companies had plans for technology transfer, out of which only 47% (n=8) had a technology transfer framework in place which in itself was not effectively working. The study concluded that there was a gap in medicines access and identified the role that can be played by technology transfer premised on a feasible framework. |
| iii. Consolidate, harmonize and streamline all relevant statutes to ensure clarity and reduce bureaucratic bottlenecks to local pharmaceutical manufacturing. | **Not done.** The Vision 2030, 2008-2012 strategic plan planned for enactment of a legal and institutional framework to harmonize regulations dealing with manufacturing and other sectors and eliminate overlaps in functions across Ministries dealing with manufacturing through review of the National Industrial Development Act. However, the Act has not been reviewed since 1967. For the pharmaceutical industry, it was noted that multiple regulatory bodies continue to govern function and practice in the pharmaceutical sector, some fall within the sector and Ministry of Health, while others are with other government ministries such as the Ministry of Industry, Trade and Investment. |

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| iv. Curb the production, distribution and sale of substandard and counterfeit medicines; and illegal sale of medicines. | **In progress.** In 2004, PPB had in place pharmacovigilance (PV) system for identification and reporting sale of substandard and counterfeit medicines; and illegal sale of medicines. Guidelines on safety and quality of medicines by PPB. PMS guidelines are in place; Review of CAP244 was amended in 2022 to include PV and PMS rules. In the PPB PMS done in 2022, it was revealed that the prevalence of poor-quality medicines in the market was 4% in 2015. From the PPB website, there were 28 products reported to have either been falsified or substandard (11 falsified products and 17 substandard products) between 2018 and 2022. |
| v. Enhance and promote the procurement, distribution and use of quality medicines. | This intervention is covered under Pillar 3, interventions 1, 2, 6 and 7 |
| vi. Develop incentive schemes for investment in local production of essential medicines to improve their affordability, availability and quality. Incentives may include local preference in public procurement, removal of taxes and duties, export incentives, fast-track market authorization, among others in line with national industrialization strategy. | This intervention is covered by intervention 1 in this pillar |
| **Pillar 5:** Improving affordability of essential medicines<br><br>**Observations:** The pillar has 14 interventions. Intervention 14 had two unrelated points and they were separated for objective evaluation. Intervention 5 and 6 were not evaluated as there were similar interventions in other pillars.<br><br>**Implementation rate:** 47%. Two interventions were fully implemented; eight were in progress and 7 were not implemented. | |
| i. Promote transparency in the pricing structure of medicines by pharmaceutical manufacturers, distributors and health service providers. | **In progress.** Discussion of pricing heightened with the prioritization of UHC in 2017 in the Big Four Agenda culminating in the establishment of Medicines Affordability and Pricing Advisory Committee (MAPAC) in 2020 to address matters of pricing and affordability. MAPAC identified ten strategies towards pricing and affordability that are at different levels of implementation. One of the activities planned for 2023 was to carry out a market price survey. |
| ii. Establish and support a multi-disciplinary mechanism to monitor and advise on medicine prices and affordability. | **In progress.** The mandate of MAPAC was to be advisory in nature for a period of three years from 2020. A blueprint for the development and implementation of HPT pricing reference system was developed in 2021 and development of a pricing database had commenced. Mechanisms for continuity of the monitoring and advisory role had not been established. |
| iii. Provide policy guidance on pricing structures for essential medicines by all categories and monitor prices and affordability of essential medicines in all sectors. | **In progress.** Draft guidelines and regulations on pricing and generic prescribing were in place. |
| iv. Institute a mechanism to monitor medicine price increases through notification to the FDA, with a view to regulating excessive increases. | **Not done.** Competition Act of 2011 provides for promotion and safeguarding competition in the national economy to protect consumers from unfair and misleading markets. Registration of HPT under PPB Cap 244 criteria focused on quality, safety, efficacy and economic value of the product, however, economic value criteria have not been implemented and was also expunged from revision 2022 of the Cap 244. |

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| v. Expand and sustain mechanisms to provide subsidized essential medicines at the primary level through the public and faith-based supply systems. | **Done.** User fees in public dispensaries and health centers were removed in 2004 and replaced with a 10/20 policy which was registration charges of 10 and 20 Kenyan Shillings. The 10/20 policy was abolished in 2013 and replaced with compensation for user fees foregone at Primary Health Care (PHC) level. There is also continued strengthening of access to essential HPT under UHC-PHC. |
| vi. Establish effective exemption mechanisms to remove financial barriers that may hinder vulnerable population groups from accessing essential medicines. | **Done.** There are available waiver and exemptions mechanisms for those unable to pay in public hospitals. UHC policy is in place and provides for the expansion of the population covered by health services with a focus on underserved, marginalized, and vulnerable populations, National Health Insurance Fund (NHIF) covers for vulnerable groups (Orphans and Vulnerable Children and the Health Insurance Subsidy for the Poor (HISP) programs implemented). The free maternity program as a presidential declaration was rolled out in June 2013 and later incorporated into NHIF in 2016 as the Linda mama program rolled out and health financing reforms underway. Some County governments have social protection schemes for vulnerable patients e.g., Muranga, Makueni, Kakamega. The expansion of prepaid insurance coverage mechanisms under NHIF in the implementation of UHC resulted in the amendment of legislation on coverage of the vulnerable population by the national government (NHIF Act amendments 2021) and there are ongoing efforts towards social health insurance. |
| vii. Establish an effective mechanism for reimbursement of the cost of essential medicines through health insurance schemes for inpatient and outpatient services. | **In progress.** The NHIF benefit package covers health services with Health products inclusive but is not explicit for medicines/HPT. Under some payment mechanisms such as capitation and reimbursement for Linda Mama program, medicines may be out of stock but facilities still make the full claim for the service. There is a need for explicit coverage for medicines at both in and out patients. |
| viii. Waive taxes and tariffs on pharmaceutical products, including raw materials, finished goods and packaging materials. | **Done.** The 2013 Value Added Tax (VAT) Act exempted finished pharmaceutical products and waste from VAT. With amendments of the VAT Act in 2014, 2015, 2016, 2018, 2021, 2022 there were tax reliefs as exempt or zero rating. For example in 2014, inputs or raw materials (either procured locally or imported) supplied to pharmaceutical manufacturers in Kenya for manufacturing of medicaments were EXEMPTED from VAT; in 2015, 14 (35%) out of 39 finished pharmaceutical product categories and inputs and raw materials were ZERO-RATED; in 2016, Antibiotics were zero rated from VAT; in 2018, Act removed medicaments containing alkaloids or derivative from zero rating and provided specific medicaments for zero-rating under alkaloids derivatives(medicaments containing ephedrine, pseudoephedrine, norephedrine, others); in 2021, more finished products exempted from VAT; in 2022, Plant and machinery of chapter 85 and 85 imported by manufacturers of pharmaceutical products or investors in the manufacture of pharmaceutical products, Medical oxygen, Urine bags, adult diapers, artificial breasts and colostomy or ileostomy bags for medical use were exempt from VAT |
| ix. Encourage and facilitate bulk procurement of pharmaceuticals, including local and regional pooled procurement where feasible. | **In progress.** Local bulk procurements were in place prior to the policy. KEMSA carries out bulk procurement for public health facilities, Donor funded HPT under the Strategic health programs (HIV, TB, malaria) are procured using pooled procurement sourcing, Draft pooled procurement guidelines by MoH are in place and focus on pooling of low demand and high-cost HPT. Mission for Essential Drugs and supplies (MEDS) carries out bulk procurement to service both faith-based, private and public health facilities. However, regional bulk/pooled procurement has not been achieved. |

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| x. Where the Government deems that specific medicines are unaffordable and that these medicines are essential to the health and well-being of a specific population group, the Government will make them available through authorized non-public health care providers at acquisition cost plus the transaction costs involved. | **Not done.** Through NHIF, patients can access high cost products such as anti-cancers from the private sector for those subscribed and paid-up. However, this is achieved at the market rate and there are no subsidies from government to non-healthcare providers nor has a mechanism for reducing cost of medicines been implemented yet. |
| xi. Promote generic prescribing in the public and private sectors through the formulation of an appropriate medicines use policy/strategy. | In progress. KEMSA procures by generic names and lists products by their generic names, The Kenya Essential Medicines List (KEML) is also published by generic names. Draft guidelines for generic prescribing and therapeutic substitutions under development. There are guidelines for establishment of Medicines and Therapeutic Committees (MTC), however, the functionality of the MTC at the county, sub county and hospital level has not been established. The MTC is a mechanism to ensure best prescribing and dispensing practices are upheld. |
| xii. Create rules and regulations that allow generic substitution in the public, faith-based and private sectors. It will be incumbent upon the pharmacist, before dispensing a prescription, to inform the patient on the benefits of generic substitution and to ensure that such substitution takes place with the full understanding and consent of the patient. | **In progress.** Draft regulations on generic prescribing and therapeutic substitutions under development |
| xiii. Affirm the right of patients to make informed decisions concerning their own health, including a choice for generic medicines. | **In progress.** This intervention is not SMART. PPB has guidelines on summary of product characteristics, patient information leaflets and labeling and guidelines on safety and vigilance of HPT. Systems for the public, Health Care Workers (HCW) and industry players to report on adverse effects and poor-quality products are in place at PPB. However, MoH patient information centers have not been established and patient awareness and education remain a gap. |
| xiv. Through the FDA:<br>a) Gazette a limited list of products that may not be substituted. | **Not done.** This intervention is not clear. It is not clear what gap/issue was being addressed |
| b) Enforce compliance with set quality standards for all medicines in the market and devise mechanisms and incentives to fast track registration of generics | **Not done.** Criteria for fast tracking is based on emergency, locally produced products and not because they are generics. |

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| **Pillar 6:** Promoting appropriate medicines use<br><br>**Observations:** This pillar had 13 interventions. Some interventions were further separated during the analysis where more than one intervention had been captured in one statement. This ended up creating a total of 19 interventions.<br><br>**Implementation rate:** 50%. Four interventions were completed, eleven were in progress and four were not done. | |
| i. Restructure and support the National Medicines and Therapeutic Committee (NMTC) to advise Government and stakeholders on the appropriate use of medicines. | **Done.** NMTC are appointed regularly over a time period and have been in place. They have had a critical mandate on oversight for clinical governance on the use of medicines and other HPT including program specific NMTCs e.g. for HIV. The NMTC has guided development of essential HPT lists (e.g., KEML version 2016, 2019; KEMSL version 2016; Kenya Essential Diagnostic List (KEDL) version 2014), and revision of national treatment guidelines. The current NMTC was appointed in March 2022. |
| ii. Through the NMTC, collect, evaluate, and disseminate systematic data on medicines utilization to monitor and act on policy adherence. | **Not Done.** This is a mandate of the NMTC, but they have not been collecting this data. |
| iii. Review and regularly update, KEMSL, Standard treatment guidelines at least every 2 years and promote their use at all levels of the health system. | **In Progress.** The Essential HPT lists have been updated but have not been regular as recommended every 2 years |
| iv. Promote the Essential Medicines Concept and evidence-based selection of medicines in all sectors | **Done.** Selection of Essential medicines uses an evidence-based criterion with reference to the WHO model list and in country clinical expertise and experience. |
| v. Training programs for health workers. | **In Progress.** There are training programs on management of HPT that contain modules on selection and which addresses the concept of essential lists. Both program specific training programs have been in place as well as an integrated training curriculum. |
| vi. Mandate health facilities and counties to establish Medicines and Therapeutic Committees (MTCs), with membership drawn from pharmacists, physicians, nursing staff, specialists, and health administrators. | **In Progress.** There are Counties and County Health Facilities that have established MTCs but the number that are established and active is not well documented. A guideline for establishment of MTCs has also been provided. |
| vii. Each MTC to adopt from KEML list of EMMS to be procured, prescribed, and dispensed in the health facility based on local disease and best evidence of therapeutic efficacy and cost effectiveness | **In Progress.** There are Counties and County Health Facilities with established MTCs that procure, prescribe, and dispense based on local disease and best evidence of therapeutic efficacy and cost effectiveness but the number that has done this is not documented. |

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| viii. Monitor therapeutic trends and other medicines use practices in the health facility and have corrective action to ensure rational prescribing and dispensing; | **In Progress.** There are Counties and County Health Facilities with established MTCs that Monitor therapeutic trends and other medicines use practices in health facilities especially for Antimicrobial stewardship/ AWaRE classification and monitoring of antibiotic prescription e.g. Nyeri County and have corrective action to ensure rational prescribing and dispensing. For Antibiotic Prescribing Audits conducted internally at the Nyeri County Referral Hospital and at Karatina County Hospital in the FY 2019/2020 reported the proportion of prescriptions with at least one antibiotic at between 42% - 61% and 31.3% – 52.4% respectively, which was high compared to the WHO recommendation of between 21% to 26%. (Nyeri CASIC Workplan 2020-22; Council of Governors (COG) Maarifa Centre; Compendium of County Innovations and Best Practices on Service Delivery, 2nd Edition) |
| ix. Develop policies and guidelines to improve use of medicines | **In Progress.** Essential HPT guidelines developed, a National drug formulary developed and draft prescription guidelines put in place. |
| x. Provide feedback to the national MTC on evidence and trends in therapeutics to guide review of STGs and EML | **In progress.** Feedback on evidence and trends in therapeutics is usually received from Counties but when prompted. Review of Essential HPT lists, and treatment guidelines involves county clinical experts appointed to TWGs who provide the requisite feedback based on practice. However, there is no defined or systematic reporting mechanism for this. |
| xi. Strengthen and enforce legislation to control and regulate the promotion of human and veterinary medicines and other therapeutically active substances, including Traditional Medicine (TM). | **Done.** PPB has developed guidance for advertisement and promotion of HPT. |
| xii. Develop mechanisms for the provision of reliable medicines information to health decision-makers at household, community and national levels, to enable them take appropriate actions. | **In Progress.** There is information provided at household, community and national levels but not structured mechanisms defined. Product information inserts available and in English, PVeRS systems available for reporting by the public, patient education in health facilities. |
| xiii. Establish and support a National Medicines and Poisons Information Service. | **In Progress.** Kenyatta national referral hospital has a poisons information center and antidotes for common poisonings have been included in the National formulary but this information is not available to the general public. |
| xiv. Involve consumers in Appropriate Medicines Use (AMU) strategies at all levels. | **In Progress.** Guidelines on Antimicrobial Resistance (AMR) safety developed and disseminated, AWaRE classification embedded in KEML 2019, national action plan on AMR developed, one health strategy developed, national Antimicrobial Stewardship (AMS) guidelines developed, AMR. County AMS officers appointed, surveillance system set up, Infection Prevention and Control (IPC) policies and guidelines developed, capacity building for health care and animal care workers ongoing as is research on AMR. There is an established Zoonotic diseases Unit at the Ministry of Health that addresses matters of animal health with relation to humans. This division has personnel from the Ministries of Health and of Agriculture & Livestock Development. The patient level interventions seem to be missing. |
| xv. Establish an effective mechanism for consumer feedback and complaints on medicines issues, | **Done.** Guidelines for lodging Complaints and Appeals at the Pharmacy Poisons Board developed and Pharmacovigilance Electronic reporting system developed (PvERS). |
| xvi. Establish a pharmaceutical desk within the Public Complaints Commission | **Not Done.** There is an Ombudsman office, who receives public complaints, but no specific pharmaceutical desk. |

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| xvii. Develop an appropriate policy, legal and institutional framework to facilitate and coordinate health-related TM activities, including research and development, regulation of TM products and the practitioners and consumer education. | **In progress.** Traditional and Alternative Medicine (TAM) database for practitioners and products in place; Good manufacturing practices for herbal medicines have been developed and PPB guidelines for registration of herbal products in place. TAM draft policy is undergoing stakeholders' engagements and TAM bill is under development. |
| xviii. Promote appropriate development and utilization of TM in such a way as to reduce the risks and maximize the benefits involved in their use. | **In Progress.** The policy documents and legal framework under development on traditional and alternative medicines are geared towards ensuring there are standards for TAM to promote safety in their production and use. There is a Division of Traditional and alternative medicines at the Ministry of health that has been providing leadership in this area. |
| xix. Promote the local production of useful and commercially viable TM for human and veterinary use. | **Not Done.** There is no collaboration between the TAM division, the Ministry of Agriculture and livestock Development and Zoonotic Diseases Unit. There are weak linkages between TM and pharmaceutical industries for commercialization of viable TM products. |
| **Pillar 7:** Pharmaceutical Research and development use<br><br>**Observations:** The pillar has a total of 6 interventions<br><br>**Implementation rate:** 58%. Two interventions were completed, three were in progress and one was not done. | |
| i. Coordinate research primarily directed at enhancing pharmaceutical services. | **Not Done.** Currently there is no one coordinating the pharmaceutical services research. We have research ongoing by Kenya Medical Research Institute (KEMRI) and academic institutions but this is not consolidated. |
| ii. Establish and maintain a medicines research database and facilitate the prioritization of research to address key health needs; | **In Progress.** Database established at MoH - The Kenya Health and Research Observatory (KHRO). The observatory still exists but it is not updated and maintained as expected. |
| iii. Foster collaborative mechanisms to promote and enhance pharmaceutical research. | **In Progress.** Collaborations exist at institution level e.g. bilateral MoUs between Kenya and Indonesia, Korea. This is a roll that should be facilitated by The Ministry of Health |
| iv. Increase support for pharmaceutical research (including operational research) and utilize research findings to further develop pharmaceutical policies and practices. | **Done.** KEMRI and academic institutions are carrying on a lot of research and during COVID 19, KEMRI carried out research that informed policy, practice and products |
| v. Encourage, motivate and support health institutions and professionals to conduct R&D on medicines including TM. | **Done.** Kenyatta University (KU) was allocated funding by National Research Fund Kenya and has developed a TAM center. KEMRI receives annual financial allocations from government though not adequate. |
| vi. Encourage and support the establishment of clinical and Bioequivalence (BE) testing centers for pharmaceutical research. | **In progress.** Guidelines on bioequivalence available; Framework for BE studies available; Expert committee on BE appointed and operational; Equipment for BE (Liquid Chromatography, Mass Spectrometry (LC-MS) for NQCL is under procurement and ongoing; BE pilot studies ongoing |

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| **Pillar 8:** Information and communication technology (ICT)<br><br>**Observations:** This pillar had 2 interventions. One intervention was further separated during the analysis where more than one intervention had been captured in one statement. This ended up creating a total of 3 interventions.<br><br>**Implementation rate:** 67%. One intervention was completed, two were in progress. | |
| i. Regulate online sale of medicines | **Done.** Guidelines of Internet Pharmacy Services established and need to be aligned to best global practices. |
| ii. Implement strategies that encourage consumers to buy medications from reputable pharmaceutical outlets. | **In Progress.** There are still unlicensed practitioners conducting online sales of pharmaceuticals. |
| iii. Invest in ICT infrastructure for effective operation of public pharmaceutical services, including procurement, distribution, regulation and quality control. | **In Progress.** have partially automated procurement of HPT through the Integrated Financial Management Information Systems (IFMIS); Counties order/procure from KEMSA through the LMIS: KEMSA have their automated warehousing management system and electronic Proof of delivery (e-POD); PPB operates a pharmaceutical regulatory information management systems (PRIMS) with automation of all services including indexing, exams, registration, retention/renewals among other services (https://prims.pharmacyboardkenya.org/); PvERS for Pharmacovigilance of HPT: Damu KE for vein to vein blood management; Chanjo Ke for vaccines management; Afya Ke digitization of HPT management at health facilities. |
| **Pillar 9:** Human resources for the pharmaceutical sector<br><br>**Observations:** This pillar had 11 interventions. Some interventions were further separated during the analysis where more than one intervention had been captured in one statement. This ended up creating a total of 15 interventions.<br><br>**Implementation rate:** 70%. Nine interventions were completed, three were in progress and three were not done. | |
| i. Develop and implement a national pharmaceutical human resource strategy. | **In Progress.** There is A Human Resource for Health Strategy at the Ministry of Health: Internship Policy for MoH: They are however broad documents on all HCW not specific to Pharmaceutical HR and also HR for the pharma industry is not effectively articulated. |
| ii. Enact legislation to recognize pharmaceutical specializations | **Not Done.** This has not been achieved |
| iii. Review and implement pharmaceutical schemes of service to attract and retain appropriate HR for the public service. | **Done.** The Scheme of service for Pharmaceutical staff was reviewed in 2016 and implemented |
| iv. Recruit and retain adequate numbers of pharmaceutical personnel in the public service in line with established health sector strategies, norms and standards. | **In Progress.** Recruitment of pharmaceutical staff has been ongoing both at the National level (UHC Staff) and Counties (through County Public Service Boards) but numbers are still below the required as per the norms and standards. Human Resources for Health Norms and Standards Guidelines for the Health Sector (2014-2018) provides cadre numbers required per level of care; The Health Labour Market analysis indicates that for Kenya to achieve its policy drive of improving the quality of life of the population by improving health service provision to achieve UHC, there is an urgent need to invest in the health workforce including Pharmaceutical staff including public sector. |
| v. Include the deployment of pharmaceutical personnel in ongoing sector strategies and initiatives for improving HR capacity in the Faith Based Health Services. | **Done.** There are guidelines for secondment in Public service developed in 2016 but it is unknown whether any pharmaceutical staff have been seconded to Faith Based Organizations. |

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| vi. Expand pharmaceutical training capacity and opportunities at colleges and universities | **Done.** Increased number of training institutions and Increased number of trained personnel (Refer to the Health Market Analysis Report) There is Continuous collaboration of training institutions with regulators and stakeholders to ensure quality of graduates is not compromised |
| vii. Create mechanisms to enable access by trainees from other countries | **Done.** University Exchange Programmes are available. |
| viii. Expand the variety and scope of postgraduate courses to meet the growing requirements for pharmacy specialists in Kenya and the sub-region. | **Done.** There are post graduate courses on Clinical Pharmacy, Pharmacognosy and complimentary medicine, Pharmacoepidemiology and pharmacovigilance, Toxicology: Guidelines on Specializations available by PPB |
| ix. Through the FDA and the Pharmacy Council Institute mechanisms for progression from diploma to degree level | **In Progress.** Kenya National Qualifications Framework Act (2014) provides for progression in education/profession levels.<br>The Kenya National Qualifications Framework (KNQF) is in place and provides a learning outcome-based qualifications framework, comprising of all educational and training sectors and all forms of learning; formal, non-formal and informal learning; East African Qualifications Framework For Higher Education (2014) in place provides the set of policies, objectives and information central to the organization, management, implementation and monitoring arrangements for the qualifications framework and applies to all types of education, modes of delivery, training and qualifications from basic to higher education, professional and vocational institutions, obtained through formal, and or non-formal, and or informal learning ;Guidance on progression from diploma to degree for pharmacy profession is under development by PPB. There are several diploma holders who have upgraded to Bpharm. " |
| x. Devise and enforce a system for continuous professional development | **Done.** Guidelines on Continuing Professional Development in Pharmacy developed and there is an active portal for Continuous Professional Development (CPD) management; |
| xi. Foster multilateral collaboration to enable mutual recognition of pharmaceutical personnel in the context of regional integration and international cooperation. | **Not Done.** This has only been done for Regulation of Health products and Technologies |
| xii. Define the competencies, roles and responsibilities of pharmaceutical practitioners at all levels | **Done.** PPB Guidelines for evaluation and assessment of pharmacy practitioners developed. In Public Sector the Schemes of Service defines the roles and responsibilities of pharmaceutical staff |
| xiii. Effectively regulate the training and practice of Pharmacy | **Done.** Pharmaceutical Staff training and practice is regulated by the PPB |
| xiv. Develop capacity and tools for the delivery of basic pharmaceutical services at the dispensary and community levels. | **Done.** Guidelines for practice developed, standard treatment guidelines developed, Job Aids available, Registers and reporting tools (manual, electronic), eCHIS, etc. |
| xv. Encourage and support the review, harmonization and regulation of pharmaceutical training curricula and standards to align with defined needs of the health sector. | **Not Done.** A desk review during the development of the HPT Supply chain strategy 2020-2025 confirmed that Pharmaceutical training curricula has not been reviewed to align with defined needs in the health sector. |

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| **Pillar 10:** Promoting access and safeguarding public health in pharmaceutical trade<br><br>**Observations:** This pillar had eight interventions. Intervention seven was not evaluated as it was related to intervention 8 and 9 in pillars 3 and 5, respectively<br><br>**Implementation rate:** 13%. One intervention was fully done, two were in progress and four not done. | |
| i. Take all necessary precautions to safeguard all the Trade-Related Aspects of Intellectual Property Rights (TRIPS) flexibilities, and to facilitate their full implementation in the production, procurement, importation and sale of essential medicines and essential health technologies for improved access. | **Not done.** This intervention was not SMART. Parallel importation is in place; however, the TRIPS have not been exploited for the benefit of the country. |
| ii. Fully integrate pharmaceuticals in trade policy decision making, by enhancing the national capacity to effectively negotiate the multiple facets of Free Trade Agreements (FTAs), and to safeguard all provisions for ensuring access to essential medicines. | **In progress.** Kenya was in the process of ratifying the African Medicines Agency treaty (AMA) to increase access to medicines; Duty-free market access under Africa Growth Opportunity Act (AGOA) for Kenyan exports to the United State of America; European Union-Kenya Economic Partnership Agreement (EPA); Kenya-United Kingdom FTA negotiations concluded; Kenya has signed up several regional FTAs East African Community (EAC), COMESA, Tripartite Free Trade Area (TFTA), African Continental Free Trade Area, Southern African Development Community, SACU; Capacity of Kenyan manufacturers to exploit export lines under AGOA agreement. |
| iii. Amend the Anti-counterfeit Act to provide for a definition of counterfeit medicines that is in line with internationally agreed definitions; and to ensure that the FDA has the requisite power to identify and act on counterfeit medicines in a manner that does not impede access to medicines. | **Not done.** The Anti-counterfeit Act defines what counterfeiting means and applies for all products. The counterfeiting of medicines and other health products has not been defined in Cap 244 but has been included in the proposed HPT bill. PPB however has vigilance systems to monitors quality, safety and substandard products and has developed regulations on the same. |
| iv. Develop a national strategy on public health, innovation, and Intellectual Property (IP), in line with the Global Strategy and Plan of Action (GSPOA), and support its implementation. | **Not done.** The strategy has not been developed. |
| v. Promote joint initiatives aimed at endowing negotiators at bilateral and multilateral trade fora with the necessary skills to uphold TRIPS safeguards in such negotiations. | **Not done.** There are no mechanisms to capacitate negotiators at bilateral and multilateral trade fora nor to monitor bilateral and multilateral trade agreements/initiatives between Kenya and other countries. |
| vi. Facilitate the country's participation in regional and international initiatives to harmonize pharmaceutical policies and regulatory systems, including mechanisms for information exchange and mutual recognition of regulatory decisions. | **In progress.** Kenya is a signatory to regional and global initiatives such as COMESA, African Medicines Agency (AMA), AGOA, Free Trade Commission (FTC) etc. However, there is limited evidence on the extent to which the country is benefiting from the initiatives |

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| vii. Facilitate the participation of relevant state and non-state actors in regional and international initiatives for enhancing access to HPT, such as national or regional pooled procurement. | This intervention is related to intervention 8 and 9 in pillars 3 and 5, respectively |
| viii. Enhance national, regional and international collaboration effectively to address issues of drug and substance abuse. | **Done.** Internationally, Kenya is guided and abides by the Single Convention on Narcotic Drugs of 1961, and later the protocol amending the Convention, and the Convention on Psychotropic Substances of 1971. Nationally, the use and safeguards on drug and substance abuse are anchored in the PPB Act CAP 244 of the laws Kenya and the Narcotics and Psychotropic Substances Act CAP 245 of laws Kenya. There is a multisectoral- National technical committee with key stakeholders coordinated by NACADA as the lead agency and comprising the following stakeholders NACADA, PPB, MoH-Principal Secretary (PS) representation, Anti-narcotics Unit (diversion); Customs, Immigration; judiciary, Director of public prosecution (DPP) to safeguard on use of controlled substances. Their mandate includes the (i) promotion of the availability and accessibility of controlled medicines for medical purposes, (ii) the prevention of abuse and dependence and (iii) prevention of diversion. |
| **Pillar 11:** Enhancing access to veterinary medicines.<br><br>**Observations:** This pillar had a total of 4 interventions<br><br>**Implementation rate:** This could not be determined as all Veterinary products were moved to be regulated under the Kenya Veterinary Board in 2015 who are under the Ministry of Agriculture and Livestock | |
| i. Enhance structures and foster collaboration between pharmaceutical and veterinary services, to ensure adequate control and appropriate use of veterinary medicines. | Regulation of Veterinary Products was taken up by the Kenya Veterinary Board in 2015 |
| ii. Require all veterinary medicines to be registered by the FDA and enforce their compliance with O.I.E code of practice for registration of veterinary medicines. | Regulation of Veterinary Products was taken up by the Kenya Veterinary Board in 2015 |
| iii. Ensure that veterinary medicines are distributed only through pharmaceutical and veterinary outlets licensed by the FDA, in accordance with relevant legal provisions. | Regulation of Veterinary Products was taken up by the Kenya Veterinary Board in 2015 |
| iv. Through the Director of veterinary Services (DVS) and in consultation with the DPS, establish a Veterinary Medicines and Therapeutic Committee (VMTC) to: determine the range of veterinary medicines to be marketed in the country and | Regulation of Veterinary Products was taken up by the Kenya Veterinary Board in 2015 |

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| **Pillar 12:** Financing for essential pharmaceuticals and pharmaceutical services<br><br>**Observations:** This pillar had a total of 7 interventions<br><br>**Implementation rate:** 64%. Two interventions were completed, five were in progress. | |
| i. Mobilize adequate financial resources, and appropriately allocate them for effective implementation of this policy and for equitable provision of pharmaceutical services. The focus in pharmaceutical financing will be on equity and efficiency. | **In Progress.** A costed HPT supply chain strategy to inform gaps; National forecasting and quantification (F&Q) done as a critical tool for resource mobilization; With declining donor funding, national and county governments have continuously allocated funds for HPT and other services; County budgets and Specific Facility Improvement Funds (FIF) Acts for ring fencing health and HPT funds: Healthcare financing reforms; Benefit packages through the NHIF like Linda mama where health facilities are reimbursed for services offered; |
| ii. Define clear financing mechanisms for essential HPT within the national health insurance benefit package and other health sector financing strategies. | **In Progress.** County Specific FIF Acts: Healthcare financing reforms; Benefit packages through the NHIF like Linda mama where health facilities are reimbursed for services offered; |
| iii. Allocate the resources required for sustained public procurement and supply of medicines and for provision of pharmaceutical services. | **In Progress.** Counties to forecast and quantify their needs for HPT; Budget allocation for HPT done for national strategic health programs' commodities and counties. However, there is limited financial allocation to supply chain systems strengthening. |
| iv. Abolish user fees for key essential medicines in the public sector. | **In Progress.** Abolishment of user fees for essential services done, especially at lower level (2 & 3) health facilities |
| v. Establish mechanisms for ring fencing of Government allocations for EMMS. | **In Progress.** County specific assenting and implementation of FIF Acts. |
| vi. Develop policy guidance on optimization of the public medicines budget, to ensure equity and allocative efficiency aligned with priority health needs and targets. | **Done.** Development and revision of Essential HPT lists (KEML, KEDL & KEMSL) |
| vii. Strengthen financial management and pharmaceutical supply systems to enable effective operation and monitoring of resource utilization | **Done.** Public finance management (PFM) reforms and PFM Act (PFMA) enacted 2012 with subsequent amendments; Increased visibility of financial transactions with implementation of IFMIS; Kenya Health facility assessment; Use of MoH Kenya Health Information Systems (KHIS) Commodity Tracking Tools and their corresponding dashboards; KEMSA eLMIS operational; Some counties conduct support supervision and supply chain audits |

# Summary of findings from the Key Informant interviews

This section of key informant interviews was done by thematic areas identified by the steering committee appointed for the evaluation of KNPP and were adopted for the policy evaluation. There were 6 thematic areas identified and the twelve pillars were appropriated accordingly as below.

1. Access, Finance & supply systems: Pillar 3, 9, 12
2. Regulation, Quality Assurance and Safety: Pillar 2 and 5
3. Pharmaceutical Industry, Trade and Local Manufacturing: Pillar 4 and 11
4. Information Communication & Technology, Innovation, Research & Training: Pillar 6 and 7
5. Legislation, Governance and Human resource: Pillar 1, 8
6. Service delivery & Appropriate use: Pillar 3, 5, 9, 10

## i. Access, Finance & supply systems:

This thematic area addressed pillar 3, Expanding availability of essential medicines, pillar 9, improving affordability of essential medicines, and pillar 12, Financing for essential pharmaceuticals and pharmaceutical services. A total of 18 key informants were targeted but only 14 (77%) were responsive. The Key informants that were responsive were from Ministry of Health strategic health program officers, public/private medical supplies agency, County health management teams, health insurance providers, donors, and implementing partners (Annex 3).

Policies and legislation that have been developed supporting this area are the Constitution of Kenya, The Health Act 2017, The Kenya Health Policy 2014-2030, The Kenya Competition Act, Consumer Act 2012, KEMSA Act 2013 and the HPT supply chain strategy 2020-2025 amongst others. With promulgation of the constitution in 2010, new structures were established in the County Governments including health, which is devolved to counties, and to manage HPT the governance units formed in all 47 counties were HPT Units.

The key informants recognized that various stakeholders have collaborated with the Government to increase availability of HPT through technical assistance to Counties and Strategic health programs for quantification and procurement/supply planning, procurement of generics and promoting generic prescribing practices, donors procuring strategic health products to reduce funding gap, the public HPT supplies authority advancing credit facilities to counties, engagement of local manufacturers of HPT, development of National commodity specific security strategies, and last mile delivery by the public HPT supplies authority amongst others.

To improve affordability of HPT, some strategies adopted include development of a market survey concept note and procedure for HPT's for the public HPT supplies authority to implement, support on price benchmarking activity was provided for a category of products and global prices shared for comparison and review by the public HPT supplies authority, landscaping activity undertaken in four counties to help them identify HPT procurement challenges, strategic health products procured through the public HPT supplies authority such as antiretrovirals leverage on healthy competition, transparency and economies of scale to bring the prices down, expanding local pharmaceutical production has enabled in-country production of some antiretrovirals thus lowering product prices, pooled procurement by donors and

procurement agencies by consolidating the requirements of many players within and even outside the country to benefit from economies of scale to lower product prices, and access programs with some pharmaceutical multinationals to access some medicines at prices that are more favourable than prevailing market rates amongst others.

## ii. Regulation, Quality Assurance and Safety

This thematic area dealt with pillar 2, the strengthening of pharmaceutical regulation of products and services and pillar 5, promoting appropriate use of medicines including traditional and alternative medicine. A total of 7 key informants were targeted but only 4 (57%) were responsive. The responses were from the PPB, NQCL, Kenya Tissue and Transplant Authority (KTTA) and National Public Health Laboratories (NPHLS).

This thematic area dealt with the strengthening of pharmaceutical regulation of products and services as well as the promotion of appropriate use of medicines including traditional and alternative medicine.

Some of the key findings from the key informant interviews include;

Reference to the FDA as the regulatory authority was misaligned as the same policy proposed its set-up and went ahead to assume that it exists and refer to it in all areas where the responsibility was for the regulator. It would have been appropriate to be generic and refer to regulatory authority rather than being specific to FDA. Additionally, proposal to form FDA was incoherent with policy assumed that it applied to all other HPT.

The regulatory functions of the PPB (the Regulator) have tremendously grown in the recent past. These functions that have had substantial growth include; Inspectorate, Clinical Trials regulation, training, human resource and practice management, appropriate use of medicines, Traditional and alternative medicine, financing for pharmaceutical sector, regional and international collaborations, quality assurance, promoting local manufacture and governance and coordination.

Changes in MoH that have resulted in the creation of the directorate of HPT was also a key finding that promises to lead to better coordination of regulation and safety of HPT

The Health Act 2017 was also cited and the realization that alignment of all other laws to it is required.

Deficiency of PMS activities as well as their funding was also highlighted. PMS is necessary in assuring the safety of commodities and is also indicator of maturing regulation.

Gaps were highlighted on Herbal products with lack of framework for regulation of product & practice, limited testing capacity, lack of African herbal pharmacopeia, no methods of analysis, no reference materials, and no testing equipment for herbals.

## iii. Pharmaceutical Industry, Trade and Local Manufacturing

This thematic area covered pillar 4 (Expanding local pharmaceutical production) and 11(Enhancing access to veterinary medicines). A total of 16 key informants were targeted and 11 (68.8%) responded. The responses were from Pharmaceutical Society of Kenya, KEMRI, National Syndemic Diseases Control Council (NSDCC), Kenya BioVax Institute, Federation of Kenya Pharmaceutical Manufacturers (FKPM), Kenya Industrial Property Institute (KIPI), PPB, Kenya Pharmaceutical Association (KPA), IQVIA, PATH and Clinton Health Access Initiative (CHAI) (Annex 3). The key feedback received from the respondents are as described below.

On the overall observations about the policy, it was reported that the thought process of the policy was well articulated, was evidence-informed and a lot was considered during its development to make it futuristic. The major problem with the policy was that the policy was not well implemented and its review took too long, given the changing dynamics of the pharmaceutical sector.

Regarding manufacturing, the majority of the respondents agreed that as a country we are still lagging behind in attaining self-sufficiency in production of Pharmaceutical products and other HPTs. Despite the Kenya local manufacturing agenda aligning with the African manufacturing plan, the levels of local manufacturing as envisioned by the policy have not been achieved due to lack or poor implementation of plans such as the GMP roadmap. Additionally, despite having the roadmap, Kenya has not fully implemented it yet other countries especially in West Africa used the roadmap and have made strides in local manufacturing. One of the major challenges for local manufacturing in Kenya is financing the investments. There is a need to look for ways to provide soft loans to local manufacturers, provide free trade zones and concessions or incentives from the government. The manufacturers acknowledged that new manufacturers have come up in the last 10 years but Government support through risk-weighted affirmative action's remains inadequate.

The TRIPS flexibilities have not been applied despite the law being in place. Policy concurrencies in manufacturing by the ministry of industrialization, trade and investment have not been implemented to favour the local manufacture. Concessions are as important as regulation and should be considered to revamping local manufacture. The government should also commit to buying what is locally manufactured. Kenya has potential to locally manufacture some excipients from raw materials locally available e.g., pharmaceutical sugar, cornstarch, sapogenin from sugar, maize and sisal, respectively. Sapogenin is a precursor for steroids and is derived from sap from sisal. Kenya also has the potential to manufacture anti-snake venoms but currently, we get venom, and it is taken to India to make the anti-venom which we have to buy back. We have snake farms in places like Baringo and Watamu and therefore we have a source of raw material. What is lacking is providing a conducive environment to support the investment.

Comparing incentives with countries like India, it was reported that India gives local manufacturers incentives like not paying taxes for 30 years, they access equipment freely for a period of six years before they start paying and this gives them an advantage to grow. The factories are spread to the rural areas and ensure they employ locals. Such concessions or incentives motivate investments in local manufacturers. you find that people then have the will to invest. In Kenya, the investors have to cover all requirements on their own. For example, Moderna has grappled with not only the regulatory part for vaccines, but also them being given some concessions by the Kenya Revenue Authority (KRA).

On innovations and Research, it was reported that as a country we have not exploited them to address medicines/HPT priority health issues. However, Biovax were working closely with KEMRI to commercialize research outcomes and had a written Memorandum of Understanding (MOU). Counties are producing their own oxygen, also manufactured various products during COVID-19 outbreak and are in process to produce their own blood and blood products as satellites. Counties can play a critical role in manufacturing and are in dialogue to provide an enabling environment - e.g. land to investors. Regional economic blocs can also be exploited.

Generally, key challenges identified that continue to curtail local manufacturing of HPT include regulatory compliance, intellectual property limitations, research and development costs, high competition in pricing from cheaper imports, manufacturing costs driven by the high energy costs, Active Pharmaceutical Ingredients (API's) are imported, lengthening the lead time and increasing production costs.

## iv. Information Communication & Technology, Innovation, Research & Training

All the respondents noted that there had not been adequate financing for ICT, research and innovation.

Thematic area 4 looked into Pillar 6 - Promotion of research and innovation in medicines to address priority health issues and Pillar 7 - Embrace ICT in all aspects of pharmacy.

A total of 7 out of 11 (64%) key informants were responsive. All informants apart from one indicated that they were fully conversant with the KNPP 2012. They also cited pillar 2,4,6,7 and 9 as those that apply to most of their institutions, specifically those of higher learning.

3 out of the 7 informants confirmed that there had been changes in the guidance of policies for HPTs some of them being the separation of the office of Director of HPTs and that of the registrar of PBB, the formation of the directorate of HPTs within the Ministry.

All the key informants unanimously indicated that there is no structured system for monitoring and evaluation of the pharmaceutical sector. The legal, administrative, and regulatory frameworks, which ordinarily require involvement of the executive and legislative arms of the National Government are actioned upon haphazardly without proper coordination that could enhance synergy and achievement of set targets.

On progress made in the attainment of self-sufficiency in local production of HPTs, 5 key informants cited growth in products manufactured locally but also stated that the country is way behind in meeting its HPT needs. To enhance local production, the following measures were suggested by the key informants: provision of strategic focus on training and skills transfer to strengthen local production, development of incubation hubs for research and development of local production, implementation of preferential procurement of locally produced HPTs including the prohibition of imports for locally produced products and incentivization of local production through tax cuts.

On innovations and research, all the respondents indicated that their institutions have been involved with varying levels of innovations though most indicated that a lot more needs to be done. Areas of actions required include dissemination of research findings, the need for quality research and coordination between academic institutions and Policy makers.

However, all the respondents noted a few challenges facing their institutions on matters of research and innovations. These include inadequate Human Resources (HR) and Mentors, low demand for research by policy makers, inadequate research grants or funding, limited time e.g. due to heavy workload and administrative duties, lack of motivation, uncoordinated research processes and need for research capacity strengthening and inadequate infrastructure. There is also sub-optimal practical research towards HPT in the counties. To address these issues the following suggestions were made: Strengthen research and innovation capacity - Prioritize funding for research and innovation - Strengthen partnership and collaboration with health ministry and other policy makers - Address HR, infrastructure, and networking inadequacies - Develop and implement strategies to encourage and promote innovations - Develop and implement strategies for quality research.

All the respondents reported that their institutions had embraced the use of ICT for management of HPTs, Pharmaceutical care, and service delivery. For example The Universities has adopted blended learning involving both the physical face-to-face lectures, as well as virtual teaching (real-time and asynchronous) Other institutions also reported that their processes were electronic to the best extents. However, the cost of electronic gadgets and software were cited as hurdles. Internet connectivity was also cited by 2 respondents. The following suggestions were made -Lower the cost of electronic gadgets and software,

Improvement of internet connectivity throughout the country. Subsequently, institutions have also embraced the use of ICT in service delivery, e.g. Blood Bank Management Information System (BBMIS); Laboratory information management system (LIMS), expanded analytics with online dashboards; PPB Electronic systems to identify registered pharmacies/chemists in the private sector and product registration information systems. Members of the public can verify whether a pharmacy/chemist is registered or not. Indeed, embracing and the regulation of use of ICT in the HPT sector was a key finding. ICT is dynamic and versatile and has found application in commodity stocks management, electronic prescribing and dispensing, e-Pharmacies. Other challenges include interconnectivity difficulties even with some regions and siloed solutions where a single system and harmonization would be appropriate;

On Human resource development for delivery of pharmaceutical services the institutions of higher learning reported to have doubled or tripled the number of graduates entering the job market on an annual basis. However, the absorption of the new pharmaceutical personnel into the job market has been declining, and a significant proportion of them are not meaningfully engaged in pharmaceutical care service delivery commensurate with their level of training/education. The Ministry of Health had also progressively reduced deployment of pharmaceutical personnel. Devolution of the health function to the County Governments had tried to solve the underemployment issue though this had not been addressed adequately. Consequently, a significant proportion of the pharmacy graduates has left the pharmaceutical sector to work in other sectors due to limited opportunities available in the pharmaceutical industry. However, the few available are well-trained and skilled to teach and undertake the country's pharmaceutical functions. A few suggestions were given.

- Ensure adequate staffing of the public schools of pharmacy in Kenya.

- The Government and the Universities offering pharmacy degree programmes should ensure the curricula are aligned to the market needs; provide the requisite infrastructure and hire sufficient qualified faculty to implement these curricula.

- Schools of Pharmacy should initiate and sustain collaborative arrangements with the pharmaceutical industries to ensure that pharmacy students are exposed to the industrial processes during the entire studentship period.

- The PPB should implement and entrench recognition of pharmaceutical specialties. This will encourage post-graduate training to bridge the critical human resources gap in priority areas such as pharmaceutical biotechnology, research and development, industrial pharmacy, quality control, and quality assurance.

- The academic staff would benefit from regular continuous training and interactions with their peers in other regions for exchange of ideas and sharing of experiences.

All the respondents noted that there had not been adequate financing for ICT, research and innovation.

## v. Legislation, Governance and Human resource

This thematic area was addressing pillar 1, revamping pharmaceutical sector governance and policy direction and pillar 8, Human resource development for delivery of pharmaceutical services. A total of 12 key informants were targeted but 9 (75%) were responsive. The responses were from KTTA, NPHLS, NQCL, PPB, CEO COG, CEO Kenya Medical Practitioners and Dentists Council (KMPDC), Chair County Executive Committee Member (CECM) caucus for Health, Chair CECM HPT Thematic Technical Committee (TTC), Chair Chief Officers of Health (COH) HPT TTC. However, the following did not respond to Chair COH Health caucus, Kenya Health professionals Oversight Authority (KHPOA) and KMLTTB.

All respondents appreciated having critical roles in their institutions in the implementation of KNPP and particularly on matters of governance and human resource. It was generally felt that KNPP was not effectively implemented as counties and national governments were settling on their new constitutional functions with a lot of push and pull leading to little embrace of the policy in its early stages.

Nevertheless, there is a deliberate push to strengthen Lab systems to meet standards e.g. (ISO accreditation), increasing staff, equipment and participating actively in post-market surveillance. There has however been the gray area of emerging technologies, it is not clear who is regulating what with Institutions overlapping or having similar /related functions but not proper coordination.

Some progress has been made as evidenced by the number of locally manufactured pharmaceuticals that have been submitted for analysis prior to registration. There has however been a challenge is local manufacture of diagnostics and other non -pharmaceuticals. NQCL is yet to align itself and expand its capacity and mandate to cover the entire scope of HPT as the testing agency for Government. Roadmap to ensure all services are on-boarded to e-citizen.

Respondents noted the following achievements in revamping Pharmaceutical Governance and Policy;

- Development of a supply chain strategy,
- Several policies that have prioritized HPT.
- Reorganization of the division to deal with all HPT at the Ministry
- Efforts towards managing appropriate pricing of medicines under MAPAC
- Ongoing work under the unbundling of the Constitution for devolved functions that touches on HPT licensure and pharmacy workforce licensure and inspections at counties.
- KEMSA Act (monopoly of KEMSA) and changes required.
- Emergency drugs and oxygen availability
- Acceptance to form HPU, HPT unit structures put in place and anchoring them in law.
- Pharmacovigilance committees and focal persons at the counties
- Availability of commodity committees
- Trainings of commodity managers among all respective cadres
- Supervision has improved
- Health literacy was noted as a gap in patients requiring patient education on self-prescribing.
- Major challenges on Pharmaceutical/HPT Governance and Policy highlighted in high costs of HPT and lack of appropriate use of medicines/ Safe administration/safe use of HPT.

Regarding human resource development for delivery of pharmaceutical services, the following was noted:

- There is a general increase in the numbers of healthcare workers and number of pharmaceutical personnel as well. eg. Post-devolution health workforce has more than doubled e.g. between 2016-2021 alone the number of healthcare workers increased by 61% from 57,000 to 97,000.
- Distribution of HCW and pharmaceutical personnel has improved e.g. ASAL areas have better distribution with the increase in colleges like KMTC.

- Pharmacists providing additional pharmacy services, therapy management, immunization with expanded role and improving access to care
- Pharmaceutical specialization has also improved.
- There is improved professionalism;
- Devolution brought services close to the people with increased services/specialized services and higher staff needs.
- Post devolution, pharmaceutical technologists are now available in rural and lower facilities for commodity management.
- Trainings done for all HPT managers has helped significantly.

The following was highlighted as necessary in improving pharmaceutical personnel resources in service delivery.

- More pharmacists are required and their increased training.
- Need for good pharmacy practice, improving the clinical skills, patient counseling, and monitoring of treatment outcomes.
- Need for continuing education in pharmaceutical personnel.
- Need to deploy supportive technology integration for safety, efficiency, and pharmaceutical service delivery
- Bringing pharmaceutical staff together with others in committees for interprofessional collaboration and embracing working as a team for patient-centered care
- Pharmaceutical personnel being culturally competent, as well as imparting their leadership, management, and mentoring skills.
- Pharmaceutical technologists are key in Primary health care.

### vi. Service delivery & Appropriate use

This thematic area was looking at service delivery appropriate use. A total of 19 key informants were targeted but only 8 were responsive. The responses were from Kijabe Hospital, Kenyatta National Hospital, Kenyatta University Teaching Referral and Research Hospital, Tenwek hospital, Mathari National Teaching and Referral Hospital and Moi Teaching and Referral Hospital, President of County Pharmacists and InSupply.

The following comprised the key feedback from the respondents.

On expanding availability for HPT, there is need for

- Accurate quantification to advocate for increased budgetary allocation.
- Current funding for some referral hospitals caters for 75% of the medicines requirements
- Undertake rationalization for some HPT categories
- Current funding is adequate for public health programs e.g. maternal health, child and neonatal health

- Do open international national tenders
- Identify reliable suppliers
- Monitor stock levels daily and take corrective action for those that reach reorder levels
- Avail HPT allocation funds at KEMSA
- Purchasing from Meds to increase availability
- Leveraging on NHIF reimbursement

On affordability, the interventions in place are:

- Lower realized prices with international open tenders (continued push for KEMSA to remain responsive)
- Cost recovery model – for some referral hospitals, markup of 10-20% for medicines for terminal/ chronic illnesses
- Negotiation for access prices (prices below prevailing market prices) for certain medicines for oncology, renal disease, some hypertension and diabetes medicines. An example is abiraterone for prostate cancer negotiated with manufacturer
- Program HPT supported by the government
- Generic substitution for brands available in the hospital
- Procurement using INN names
- Identification of prequalified suppliers
- NHIF accredited facilities for chronic illness
- Using requests for quotations (RFQs) for purchases above Ksh. 50,000
- Long term options for leasing and placement of equipment with counties paying for consumables affordably

On promotion of appropriate use of medicines, the interventions in place are:

- Rigorous process of review of evidence for safety and efficacy
- Team reviews on evidence in various specialty areas
- Development of protocols and guidelines to manage various conditions
- Utilization of the Hospital Formulary
- For antibiotic use, antimicrobial stewardship committees (under the medicines and therapeutics committee) guides on use of antimicrobials
- Development of empiric antibiotics guideline in collaboration with the laboratory department
- Use of Surgical prophylaxis guidelines
- Generic prescribing of medicines

- Documentation of medication errors and sharing reports with the medical team for intervention.
- Audits to identify problem areas and mitigate against future occurrences
- Reporting on ADRs.

On Promotion of research and innovation, interventions in place include:

- Studies on patterns of AMR
- For antimicrobial stewardship (AMS) - monitor prescribing patterns
- Participate in clinical trials
- Drug utilization reviews for prescribed medicines
- Practicing Medication Therapy Management (MTM)

Ongoing studies at the methadone clinic leading to change in practice

- On financing essential pharmaceuticals
- Funding in some institutions isn't adequate
- NHIF does not reimburse on time for some institutions. 75% of revenue is from collections from different departments and also from social recovery areas.
- Counties optimizing local resource mobilization for health;
- Advocacy for increased exchequer investments in health and to go to HPT
- Facility ring fencing of funds which is key to HPT procurement resources

On improving patient adherence to medication, and good quality of HPT feedback

- Proper medication use counseling
- Giving patient appointments for review
- Include contacts of the hospital pharmacy on medicine labels for patients to call back as regards their medication
- Pharmacovigilance reports to PPB on ADRs

On measures put in place to ensure HPT are of good quality:

- Poor quality products reported within the hospital and to PPB
- Liaising with suppliers when poor quality HPT are delivered
- Obtaining feedback on analysis of the product
- Undertaking quality assays in collaboration with PPB, NQCL and DARU
- Other interventions that should be considered for HPT:
- Explore pooled procurement mechanisms for selected HPT

- Strengthen local manufacturing for HPT
- MoH to work closely with and support National Referral Hospitals
- Undertake Health Technology Assessment implementation for the Country and at the facility level

Solutions

- Lack of costed pharmaceutical services and standardized mark ups and pricing guide to all health facilities to ensure uniformity
- Need to tap into NHIF reimbursements to cover HPT
- Strict adherence to KEML and other essential HPT lists
- Encourage best prescription practices such as use of INN
- Encourage local manufacturing of HPT
- Create awareness and capacity building of Healthcare workers on best prescribing practices
- Support for Medicines and therapeutics committees.
- There's no economic and efficient strategic sourcing and procurement of generic medicines
- Lack of transparency in the marketplace about quality suppliers, competitive prices, product traceability to enable informed choices for buyers and end users.
- Use of EMR to reduce on paper-based prescription that is KEML derived leading to adherence to standard treatment guidelines
- CMEs and proper induction of healthcare workers,
- Prescription audits
- Provide direction in funding of supply chain and HPTU activities.
- Strengthening implementation of good pharmacy practices in line with global standards and reinforcing and regulating achievement and maintenance of those practices.
- Enforce and strategically implement newly developed standards of practice to ensure appropriate medicine use across all levels.
- Coordinate and collaborate with partners and stakeholders to utilize resources to support and establish a shared vision for patient centered care and supply chains that better serve all Kenyans across public and private sectors with improved health outcomes.

# 5. Recommendations

To have a HPT policy that envisions a well-governed sector that would promote access to essential health products and Technologies to all Kenyans and contribute to social and economic development.

The KNPP was mainly referring to pharmaceuticals despite indication in the preamble that it represented all HPT. The policy for development is to encompass all HPT that include medicines, medical supplies, medical equipment, and all other technologies. This will allow the adoption of the new policy by the wide HPT sector.

The KNPP 2012 evaluation was difficult due to lack of an implementation framework. The policy to be developed should have a costed implementation framework with a clear monitoring and evaluation plan.

The interventions identified for the policy should be SMART- Specific, Measurable, Attainable, Realistic and Time Bound. This will allow for development of clear performance indicators.

The development of the policy should ensure comprehensive stakeholder mapping and engagement for buy-in and support for implementation.

# 6. Conclusion

A new policy is due for development that addresses all HPT that incorporates consideration that health is a devolved function to County governments with National government.

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# 7. Annexes

## 7.1. Annex 1: Desk review standard tool

| PILLAR No: | | | | | |
|---|---|---|---|---|---|
| Key Issues and Challenges as outlined in KNPP: | | | | | |
| What was to be done | What has been done | What is being done | What has yet to be done | Key stakeholders | Reference documents |
| Intervention 1: | | | | | |
| Intervention 2: | | | | | |
| Intervention 3 | | | | | |

## 7.2. Annex 2: Steering Committee Members

| | Name | Role | Organization |
|---|---|---|---|
| 1 | Dr Nancy Njeru | Chairperson | Ministry of Health |
| 2 | Dr Tracy Njonjo | Secretary | Ministry of Health |
| 3 | Dr Kefa Bota | Secretariat | Ministry of Health |
| 4 | Dr Eunice Gathitu | Secretariat | Ministry of Health |
| 5 | Dr Stephen Njuguna | Secretariat | Ministry of Health |
| 6 | Dr Susan Njogo | Secretariat | Africa Resource Centre |
| 7 | Clara Namidi | Secretariat | Ministry of Health |
| 8 | Richard Gatukui | Secretariat | Ministry of Health |
| 9 | Dr Diane Sibi | Secretariat | Kajiado County |
| 10 | Dr Titus Isoe | Secretariat | Meru County |
| 11 | Dr James Kimotho | Member | KEMRI |
| 12 | Dr Amos Oyoko | Member | Ministry of Health |
| 13 | Dr Dipti Bhavsar | Member | Mathari National Teaching and Referral Hospital |
| 14 | Dr Hillary Kagwa | Member | Kiambu County |
| 15 | Esther Sigilai | Member | Ministry of Health |
| 16 | Rose Ngara - Muraya | Member | KIPPRA |
| 17 | Meboh Abuor | Member | Council of Governors |
| 18 | Dr Michael Lusiola | Member | Kenya Biovax Ltd |
| 19 | Lucas Mwago | Member | Ministry of Investment, Trade and Industrialization |
| 20 | Dr Kigen Bartilol | Member | Ministry of Health |
| 21 | Dr Mathayo Kwena | Member | National Quality Control Laboratory |
| 22 | Dr Joyce Wamicwe | Member | Ministry of Health |
| 23 | Professor Shital Maru | Member | The University of Nairobi |
| 24 | Chief Executive Officer | Member | Pharmacy and Poisons Board |
| 25 | Chief Executive Officer | Member | Kenya Medical Supplies Authority |

## 7.3. Annex 3: List of Contributors

| | Name | Role |
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| 4 | Dr. Kefa Bota | Ministry of Health, Kenya |
| 5 | Dr. Nancy Njeru | Ministry of Health, Kenya |
| 6 | Dr. Pauline Duya | Ministry of Health, Kenya |
| 7 | Dr. Sarah Mwangi | Ministry of Health, Kenya |
| 8 | Dr. Stephen Njuguna | Ministry of Health, Kenya |
| 9 | Richard Gatukui | Ministry of Health, Kenya |
| 10 | Clara Namidi | Ministry of Health, Kenya |
| 11 | Dr. Abdullahi Omar | Ministry of Health, Kenya |
| 12 | Dr. Albert Ndwiga | Ministry of Health, Kenya |
| 13 | Dr. Amos Oyoko | Ministry of Health, Kenya |
| 14 | Dr. Dipti Bhavsar | Ministry of Health, Kenya |
| 15 | Dr. Emmah Nyandigisi | Ministry of Health, Kenya |
| 16 | Dr. Ernest Mbae | Ministry of Health, Kenya |
| 17 | Dr. Evans Imbuki | Ministry of Health, Kenya |
| 18 | Dr. George Walukana | Kenya Medical Supplies Authority |
| 19 | Dr. Gerald Macharia | Ministry of Health, Kenya |
| 20 | Dr. Jarred Nyakiba | Ministry of Health, Kenya |
| 21 | Dr. Michael Lusiola | Kenya Biovax Institute |
| 22 | Esther Sigilai | Ministry of Health, Kenya |
| 23 | Dr. Sam Nyingi | Africa Resource Centre |
| 24 | Dr. Susan Njogo | Africa Resource Centre |
| 25 | Lynda Achieng' | Africa Resource Centre |
| 26 | Dr. Bettinah Ngei | County Government, Isiolo |
| 27 | Dr. Claver Kimathi | County Government, Isiolo |
| 28 | Dr. Diane Sibi | County Government, Kajiado |
| 29 | Fred Githinji | County Government, Kajiado |
| 30 | Dr. Hillary Kagwa | County Government, Kiambu |
| 31 | Dr. Nkatha Mutungi | County Government, Machakos |
| 32 | Dr. Titus Isoe | County Government, Meru |
| 33 | Dr. Ruth Koech | County Government, Nandi |
| 34 | Gifton Mokaya | County Government, Taita Taveta |
| 35 | Esther Njenga | Chartered Institute of Procurement and Supply, Kenya |
| 36 | Dr. Susan Outa | County Government, Busia |
| 37 | Dr. Maureen Nafula | Consultant, World Bank |
| 38 | Dr. David Kariuki | Kenya Medical Practitioners and Dentists Council |
| 39 | Dr. Cecilia Wanjala | Kenya Medical Research Institute |
| 40 | Dr. James Kimotho | Kenya Medical Research Institute |

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| 41 | Caroline Anunda | Kenya Medical Supplies Authority |
| 42 | Julius Mureithi | Kenya Medical Supplies Authority |
| 43 | Dr. Dennis Kirubi | Kenya Medical Training College |
| 44 | Luca Mwago | Ministry of Industry, Trade and Investment |
| 45 | Dr. Wycliffe Nandama | Mission for Essential Drugs and Supplies |
| 46 | Dr. Dennis Thirikwa | Moi Teaching & Referral Hospital |
| 47 | Dr. Samson Kuhora | National Health Insurance Fund |
| 48 | Dr. Serah Muteru | National Quality Control Laboratory |
| 49 | Angella Lang'at | National Syndemic Diseases Control Council |
| 50 | Josephine Kaberia | National Syndemic Diseases Control Council |
| 51 | Dr. Mathayo Kwena | National Quality Control Laboratory |
| 52 | John Paul Omollo | PATH Kenya |
| 53 | Dr. Josphat Samoei | PATH Kenya |
| 54 | Dr. Lucas Nyabero | Pharmaceutical Society of Kenya |
| 55 | Dr. Fred Siyoi | Pharmacy and Poisons Board |
| 56 | Dr. Dorothy Memusi | Pharmacy Consultant |
| 57 | Dr. Emmanuel Wamalwa | Team of Expert, Council of Governors |
| 58 | Dr. Samson Juma | Tenwek Hospital |
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| 65 | Yasmin Chandani | InSupply Health |
| 66 | Dr. Lily Kimuhu | Jomo Kenyatta University of Agriculture & Technology |
| 67 | Sammy Ziro Lewa | Kenya Industrial Property Institute |
| 68 | Rose Muraya | Kenya Institute of Public Policy Research |
| 69 | Mr Eric Sedah | Kenya Pharmaceutical Association |
| 70 | Dr. Gratia Muyu | Kenya Tissue and Transplant Authority |
| 71 | Dr. Alfred Birichi | Kenyatta National Hospital |
| 72 | Dr. Anthony Kamau | Kenyatta University Teaching, Research & Referral Hospital |
| 73 | Dr. Elizabeth Irungu | Kijabe hospital |
| 74 | Dr. Joseph Mutungi | Mathari Teaching & Referral Hospital |
| 75 | Kennedy Mugambi | Clinton Health Access Initiative |
| 76 | Philip Muchiri | Clinton Health Access Initiative |
| 77 | Meshack Ndolo | IQVIA |
| 78 | De Jong Yvon | IQVIA |

## 7.4. Annex 3: Key informants by thematic area

| | Thematic Area | Pillars | Key Informants Interviewed |
|---|---|---|---|
| 1 | Access, finance and supply systems | Pillar 3: Expanding availability of essential medicines.<br>Pillar 5: Promoting appropriate use of medicines including traditional medicines.<br>Pillar 10: Enhance access to veterinary medicine.<br>Pillar 11: Promote access and safeguarding health in pharmaceutical trade.<br>Pillar 12: Mobilize and appropriately allocate financial resources for equitable provision of pharmaceutical services. | KEMSA, NHIF, MEDS, NASCOP, RNMCAH, TB program, Malaria program, Chair County Pharmacists forum, CIPS,USAID, World Bank, ARC, Division of Immunization |
| 2 | Regulation, Quality Assurance and Safety | Pillar 2: Strengthen pharmaceutical regulation of products and services. | PPB, NQCL, NPHLS, KTTA, MSH, WHO, KEBS |
| 3 | Pharmaceutical Industry, Trade and Local Manufacturing | Pillar 4: Expanding local pharmaceutical production. | UoN, KU, USIU, JKUAT, MKU, KMTC, KEMRI, ICT Ministry, MoH DH Directorate, VIA Global, HELP Logistics |
| 3 | Pharmaceutical Industry, Trade and Local Manufacturing | Pillar 4: Expanding local pharmaceutical production. | UoN, KU, USIU, JKUAT, MKU, KMTC, KEMRI, ICT Ministry, MoH DH Directorate, VIA Global, HELP Logistics |
| 4 | Information Communication & Technology, Innovation, Research & Training | Pillar 7: Promotion of research and innovation in medicines to address priority health issues.<br>Pillar 8: Human resource development for delivery of pharmaceutical services | UoN, KU, USIU, JKUAT, MKU, KMTC, KEMRI, ICT Ministry, MoH DH Directorate, VIA Global, HELP Logistics |
| 5 | Legislation, Governance and Human resource | Pillar I: Revamping pharmaceutical sector governance and policy direction<br>Pillar 9: Improving affordability of essential medicines. | Chair CECM caucus, Chair CECM HPT TTC, Chair CoH – HPT TTC, KPA, KMPDC, COG<br>NCK, COC |
| 6 | Service delivery & Appropriate use | Pillar 3 - Expanding availability of essential medicines<br><br>Pillar 5 - Improving affordability of essential medicines<br><br>Pillar 6 - Promote appropriate use of medicines | KNH, KUTRRH, Tenwek Hospital, Kijabe Hospital, MTRH, MNTRH, County Pharmacists President, Insupply Health |
| 7 | Others | | DHPT, Division Heads, Deputy Director General (DDG), Director General (DG) |


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