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REPUBLIC OF KENYA

Ministry of Health

PHARMACY AND POISONS BOARD

KENYA VIGILANCE MONITORING AND EVALUATION FRAMEWORK AND KEY PERFORMANCE INDICATORS

(2022-2025)

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For clarifications, comments, or suggestions, please contact:
The Chief Executive Officer Pharmacy and Poisons Board
P.O. Box 27663 – 00506, Nairobi
Telephone: 0709 770 100, 0795 734 049
Email: info@pharmacyboardkenya.org, pv@pharmacyboardkenya.org
Website: www.pharmacyboardkenya.org

HPT/PDS/VMS/GUD/087	**Kenya Vigilance Monitoring and Evaluation Framework and Key Performance Indicators (2022-2025)**	**Revision No:0**	**Effective date:** 23/01/2023 **Review date:** 01/01/2026

Prepared by Principal Regulatory Officer

Name..DR. CHRISTABEL KHAEMBA.....

Sign.....

Date....17/01/2023.....

Reviewed by Director

Name..Dr AHMED I. MOHAMED.....

Sign.....

Date.....19/01/2023.....

Checked by HQM

Name..Immaculate Naibei.....

Sign.....

Date....19/01/2023.....

Authorized by Chief Executive Officer

Name..DR FRED MOIN SIYOI.....

Sign.....

Date....19/1/2023.....

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Abbreviations and Acronyms

ADR	Adverse Drug Reaction
CHMT	County Health Management Team
FBO	Faith Based Organization
KNBTS	Kenya National Blood Transfusion Services
MAH	Marketing Authorization Holder
MTaPS	Medicines Technologies and Pharmaceutical Services
NASCOP	National AIDS and STI Control Programme
NGO	Non-Governmental Organization
NLTP	National Leprosy and Tuberculosis Programme
NMCP	National Malaria Control Programme
NMRA	National Medicines Regulatory Authority
NTDP	Neglected Tropical Diseases Programme
NVIP	National Vaccine and Immunization Programme
PPB	Pharmacy and Poisons Board
PV	Pharmacovigilance
PvERs	Pharmacovigilance Electronic Reporting System
RH	Reproductive Health
RMP	Risk Management Plans
SCHMT	Sub County Health Management Team
WHO	World Health Organization

Acknowledgements

The Pharmacy and Poisons Board wishes to express its sincere appreciation to all individuals and institutions for their valuable contribution, participation and collaborative efforts towards the development of these Kenya Pharmacovigilance Monitoring and Evaluation Framework and Key Performance Indicators (2022-2025). The preparation of the Framework and Key Performance Indicators entailed the engagement and wide consultations with the stakeholders.

The Key Performance Indicators have been adapted from the Harmonized indicators for assessing and monitoring pharmacovigilance systems in East African Community partner states: user manual, The WHO: pharmacovigilance indicators: a practical manual for the assessment of pharmacovigilance systems and the indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries.

Foreword

The World Health Organization defines Pharmacovigilance (PV) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. The scope of Pharmacovigilance continues to widen to include reporting of adverse events due to blood products, biologicals, vaccines, health technologies, herbal products, traditional and complementary medicines, cosmeceuticals hence the term "Vigilance".

A PV system is "a system used by an organization to undertake its legal duties and responsibilities about PV and to monitor the safety of authorized medicinal products and identify any changes in the risk-benefit balance. An effective PV system supports the early detection, assessment, understanding and mitigation of adverse outcomes associated with medicines and medical products PV systems support the collection of data to support decision-making about medicines at various levels of healthcare systems. Regulators rely on this data to inform regulatory actions such as drug withdrawals, drug recalls, change of product labels, and drug safety alerts among others.

Therefore, it is crucial to have a robust pharmacovigilance system in place that allows continuous monitoring of the Health Products and Technologies. The Vigilance Monitoring and Evaluation Framework and Key Performance Indicators will provide a set of measures that will be critical to assess, monitor and evaluate the various constituents of the pharmacovigilance system in Kenya. These indicators will measure the existence and performance of key pharmacovigilance structures and processes, enabling identification of strengths and weaknesses as well as tracking achievements and growth (or lack thereof) in the pharmacovigilance systems. They will also measure the degree of attainment of set strategic objectives.

Introduction

1. Background

In the 1950s, the thalidomide tragedy triggered the need for a systematic way to monitor the safety of medicines. This propelled the growth of pharmacovigilance. In 1968, the WHO Programme for international drug monitoring was established which developed a platform for the database for individual case safety reports, VigiBase. VigiBase, the WHO global database is domiciled in the Uppsala monitoring center (UMC), Sweden. Pharmacovigilance has evolved over time and the data generated has influenced various policy decisions globally.

Pharmacovigilance (PV) is defined as "science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems." Pharmacovigilance is crucial as information collected during the pre-marketing phase of drug development may not capture the entire spectrum of Adverse Drug Reactions (ADRs). This is in view of the fact that:

i. Tests in animals are insufficient to predict human safety;
ii. Patients used in clinical trials are selected and limited in number and the conditions of use differ from those in clinical practice and the duration of trials is limited;
iii. By the time of licensing less than 5000 human subjects are exposed to a drug which allows only the more common ADR to be detected;
iv. At least 30,000 people need to be treated with a drug to be sure that you do not miss at least one patient with an ADR which, has an incidence of 1 in 10,000 exposed individuals. Furthermore, information about rare but serious adverse reactions, chronic toxicity, use in special groups (such as children, the elderly or pregnant women) or drug interactions is often incomplete or not available. Therefore, post marketing surveillance is important to allow detection of less common, but sometimes very serious ADRs.

The Pharmacy and Poisons Board is mandated to regulate Health Products and Technologies under the Health Laws (Amendment) Act, 2019 and the Pharmacy and Poisons Act, Cap 244, Laws of Kenya. PPB is responsible for ensuring quality, safety and efficacy of Health Products and Technologies in the Kenyan market. Pharmacovigilance is carried out by the unit of Pharmacovigilance & Post Market Surveillance under the Directorate of Health Products and Technologies at PPB.

1.1 Legal framework

The regulation for the conduct of pharmacovigilance activities is governed according to Pharmacy and Poisons Act, Cap 244 Laws of Kenya Subsidiary Legislation, Pharmacy, and Poisons (PV/PMS) Rules 2022 charted out in the mission "to protect the health of the public by regulating the profession of pharmacy and ensuring quality, safety and efficacy of Health Products and Technologies."

1.2 PV system in Kenya

The National Pharmacovigilance System was officially launched in June 2009 and falls under the Ministry of Health. The system comprises of a national spontaneous reporting system which has both the electronic and manual pharmacovigilance reporting forms and a national database known as Pharmacovigilance Electronic Reporting systems (PvERS).

The PV system stakeholders comprise of the public, private and NGO/mission healthcare providers, public health programs, pharmaceutical industry and marketing authorization holders. The PPB also works closely with other Ministry departments and programs. Figure 1 below illustrates the PV system

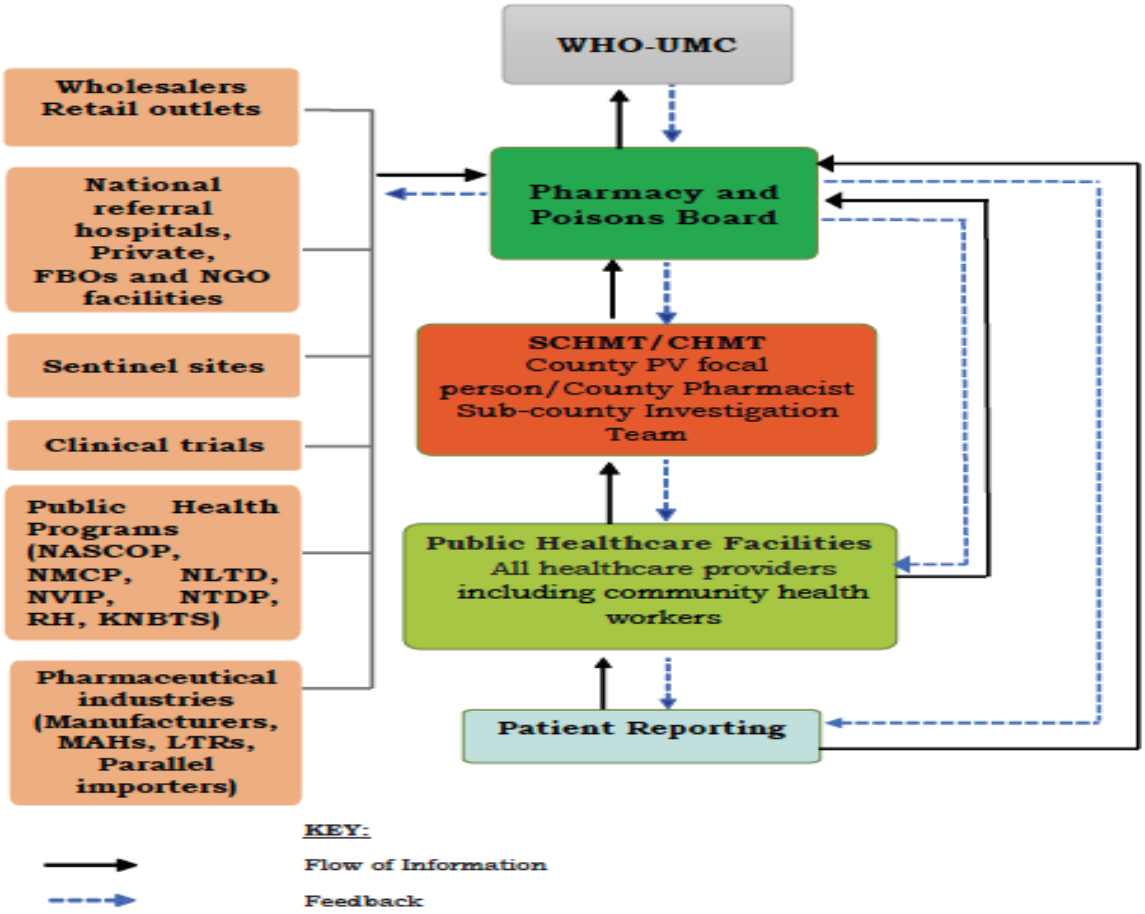


Figure 1: PV system in Kenya

2. Rationale, Scope and Objectives

The development of the Kenya pharmacovigilance Monitoring and Evaluation Framework and Key Performance Indicators was brought about by need to strengthen the PV system in Kenya. The entities under focus include:

- National Medicine Regulatory Authority
- Public Health Programs
- Health Facilities
- Marketing Authorization Holders

The indicators and associated tools will enable stakeholders to assess the status of their pharmacovigilance system and identify the system's strengths, weaknesses, and gaps; to design and plan interventions based on findings,

existing regulatory capacity and available resources; to monitor and evaluate pharmacovigilance and medicine safety activities.

The goal of the Kenya pharmacovigilance Monitoring and Evaluation Framework and Key Performance Indicators is to provide a set of measures with which to assess, monitor and evaluate the various constituents of the PV system in Kenya.

The specific objectives of the tools for assessing pharmacovigilance systems are:

1. To assess the status of the pharmacovigilance system of the various entities of the PV system in Kenya.
2. To provide indicators for the monitoring and evaluation of pharmacovigilance activities, system capacity and performance.
3. To identify gaps that will provide information for the stakeholders to take appropriate, evidence-based action in ensuring drug safety.
4. To enable evaluation of the outputs, outcomes and impact of pharmacovigilance systems.

3. Indicators

Indicators are a set of quantifiable measures that are used to gauge the performance of an organization or programme over time to be able to identify strengths, weakness, achievement, growth and impact. The indicators are measures of inputs, process, outcomes, outputs and impact of development projects, programmes or policies related to health systems and services.

Core indicators are considered essential and are based on the minimum requirements for a functioning national pharmacovigilance system defined by WHO and EAC's specific objectives and activities under the PV harmonization program. Core indicators are factored into the overall score of the PV system being assessed. Supplementary indicators are related to more sophisticated aspects of a PV system and/or aspects that are of interest but not essential, and thus are not included in the score.

Kenya pharmacovigilance Monitoring and Evaluation Framework and Key Performance Indicators comprises of:

- Forty-two (42) indicators for NMRAs and national pharmacovigilance centers – 30 core and 12 supplementary.
- Sixteen (16) indicators for public health programs (PHP) – 8 core and 8 supplementary.
- Seven (7) indicators for health facilities (HF) – 2 core and 5 supplementary.
- Three (3) supplementary indicators for marketing authorization holders (MAH).

The indicators are further classified as "structural," "process," or "outcome" according to the component of the system or type of result that they measure. They are defined as:

Structural are those that assess the pharmacovigilance systems and mechanisms, availability of basic infrastructure required to enable PV operations. They further assess the existence of a policy and regulatory framework which enables PV system to operate.

Processes are those that focus on the activities which describe the mechanism of PV which include collection, collation, analysis and evaluation of the PV reports.

Outcomes are those that measure the effects of the PV activities to ensure patient safety.

The indicators address five components of the pharmacovigilance and medicine safety system:

1. Policy, law, and regulation.
2. Systems, structures, and stakeholder coordination.
3. Signal generation and data management.
4. Risk assessment and evaluation.
5. Risk management and communication.

4. Data sources

The data will be collected from four sources within the health system:

A. **Ministry of Health/Pharmacy and Poisons Board** – PPB is responsible for monitoring HPT safety and implementing pharmacovigilance activities for the country. It is the primary source of information and data for the indicators. The data will come from the responses of key PPB and PV department staff members to assessment questions, documents and other materials developed and used by PPB as well as any databases maintained at the national level.

B. **Public health programs (PHP)** – A sub-set of indicators target specifically specialized health programs, which have a significant role to play in monitoring the safety of the HPT used for their target disease(s). PHPs to be considered for inclusion in the baseline assessment and ongoing monitoring and evaluation of PV include but not limited to; NASCOP, NTLP, NVIP, NMCP, RH, and NLTD.

C. **Health facilities (HF)** – A selection of health facilities, which should be representative of the country in terms of facility type/level, geography and sector, will be included in the assessment to provide information on the extent to which HFs are engaged in PV activities and contributing to the national system.

D. **Marketing Authorization Holders (MAH)** – A selection of marketing authorization holders will be included in the assessment to provide information on the extent to which, MAHs conduct PV activities to monitor the safety of their registered products and contribute to the national system.

5. Data collection

Data collection and analysis will be critical in monitoring progress on performance of the PV system. The information from assessment will be useful for decision-making to ensure the targets are met for the various indicators.
The indicator data to be collected are either qualitative or quantitative. The data for the structural indicators are mainly qualitative, whereas those for

process and outcome or impact indicators are quantitative. The frequency of collection of indicator data will either be quarterly, annually or 3 years. A baseline assessment will be conducted to assess the current status followed by routine monitoring and evaluation in the subsequently as specified in the framework.

6. Implementation Process

To achieve a strengthened PV system stakeholder collaboration will be paramount. Therefore, stakeholder engagement will be carried out so that the stakeholders can align their organizational PV activities to those of the national PV system. Furthermore, implementation of the national PV framework seeks to leverage on existing reporting systems. In instances where there lacks a reporting system then these systems shall be established jointly with the stakeholders. The developed M & E framework and key indicators plan will be used to lobby for funds to ensure that PV activities are carried out seamlessly. Regular assessment of the various components of the PV system will be done and PPB will be mandated to give an annual report to the stakeholders on the status of the PV system. The indicators will be implemented through a phased approach to allow the various key stakeholders adequate time and resources for planning.

7. Dissemination Plan

The national monitoring and evaluation framework and key performance indicators will be disseminated through various workshop and stakeholder's forum.

8. References

1. Guidelines on the safety and vigilance of medical products and health technologies, Pharmacy and Poisons Board, September 2019.

2. *Harmonized indicators for assessing and monitoring pharmacovigilance systems in East African Community partner states: user manual*

3. Strengthening Pharmaceutical Systems (SPS) Program. 2009. *Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries*. Submitted to the U.S. Agency for International Development by the SPS Program. Arlington, VA: Management Sciences for Health.

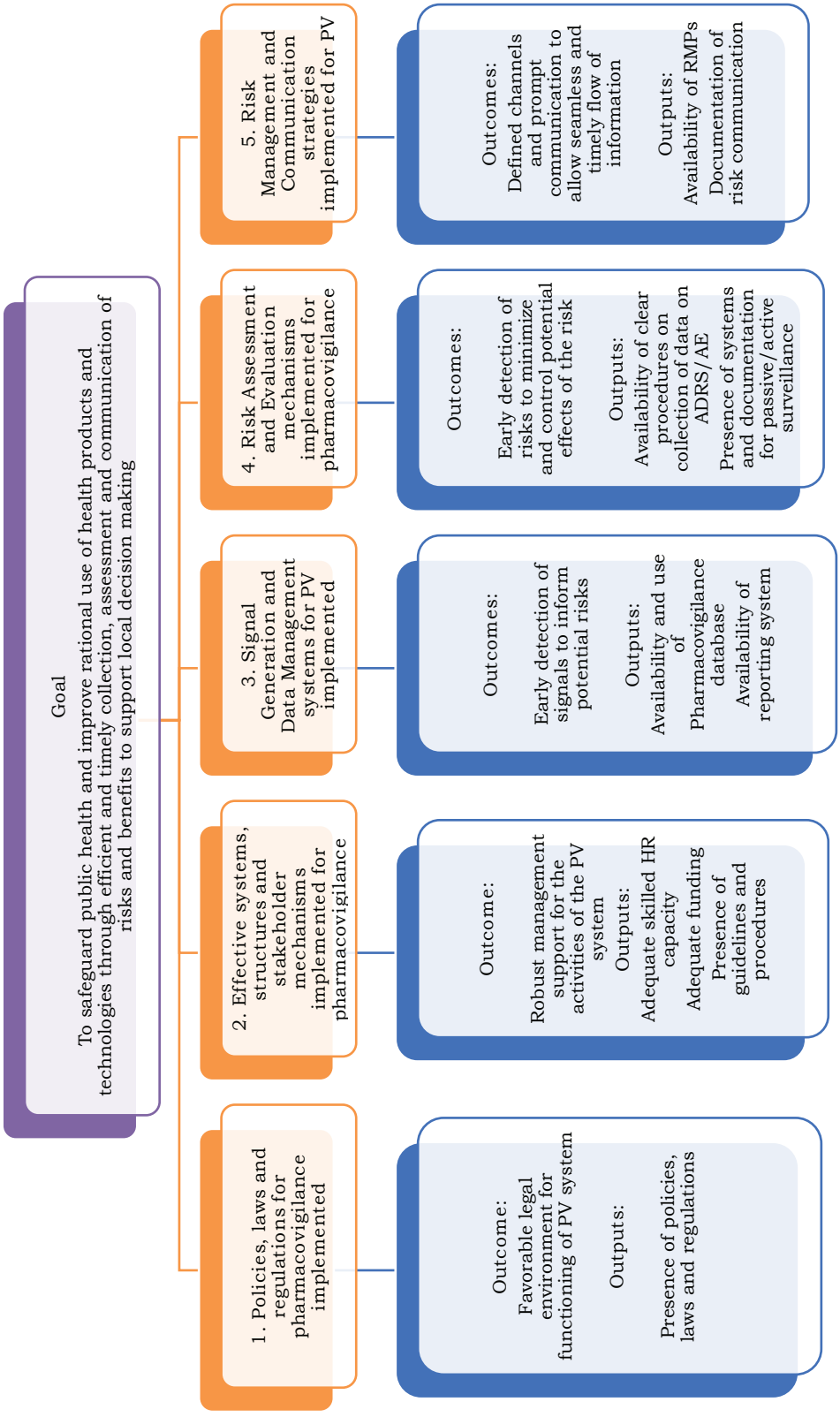
4. World Health Organization (WHO). 2015. *WHO: pharmacovigilance indicators: a practical manual for the assessment of pharmacovigilance systems.*

9. List of contributors

Dr. Fred Siyoi	Chief Executive Officer, Pharmacy and Poisons Board (PPB)
Dr. Ahmed Mohammed	Director, Health Product and Technologies, PPB
Dr. Kariuki Gachoki	Deputy Director, Product Safety, PPB
Dr. Khaemba Christabel	Product Safety, PPB
Dr. Mandale Martha	Product Safety, PPB
Dr. Nambwa Pamela	Product Safety, PPB
Muthuri George	QMS, PPB
Dr. Kusu Ndinda	Country Project Director, Medicines Technologies and Pharmaceutical Services (MTaPS)
Dr. Elias Onyango	MTaPS
Dr. Joseph Mukoko	MTaPS
Dr. Margaret Ambetsa	Ministry of Health
Dr. Brenda Onyancha	Ministry of Health
Dr. Robert Kamau	Ministry of Health

10. Annexes

Annex 1: Kenya Vigilance Monitoring and Evaluation Framework



Annex 2: Key Performance Indicators

a) National PV Centre

Key: Immediate (0-6months, Short Term (6-12 months), Long Term (More than 1 year)

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
1.1	C	S	Existence of a policy document that contains essential statements on pharmacovigilance or safety of medicines, health products and technologies (stand alone or as a part of some other policy document)	3 years	Is there a national policy on pharmacovigilance or medicine safety, or a more general medicines policy that contains essential statements?	Yes	Availability of updated National policy on safety of HPTs	Kenya National Pharmaceutical Policy	MoH, Director of Pharmaceutical Services	Annual report	
					When was the policy last reviewed? *Request documentation to verify.*	2010					

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
1.2	C	S	Existence of specific legal provisions for pharmacovigilance in the national medicine's legislation or similar legislation	3 years	Are there legal provisions for pharmacovigilance or medicine safety in the medicines act or law? *Request documentation to verify.*	No	Availability of legal provisions for pharmacovigilance	Cap 244	CEO, PPB		
1.3	C	S	Legal provisions for Marketing Authorization Holders to monitor and report the safety and quality of their products	3 years	Are there updated laws or regulations for marketing authorization holders to conduct post marketing safety activities? *Request documentation to verify.*	No	Availability of legal provisions for MAHs to conduct Post marketing activities	Cap 244	CEO, PPB		
					Are there updated laws or regulations for marketing authorization holder to report	No	Availability of legal provisions for MAHs				

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
					adverse drug reactions/medicine safety related issues? *Request documentation to verify.*		to report ADRs/ Medicine safety related issues				
1.4	C	S	Existence of updated National Essential Medicines List that was reviewed with consideration of medicine safety information	3 years	Is there an essential medicines list in use?	Yes	Availability of updated National Essential Medicines	Updated Kenya Essential Medicines List	Chair, NMTC	Workshop report	
					Does the essential medicines list selection committee consult medicine safety information?	Yes					
					When was the list last reviewed? *Request documentation to verify.*	2019					
Component 2. Systems, Structures, and Stakeholder Coordination											
2.1	C	S	Existence of a national pharmacovigilance center with	3 years	Is there a national pharmacovigilance center or any other body	Yes	Existence of PV centre	Updated PPB Strategic Plan	CEO, PPB	PPB Strategic Plan	

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			a clear mandate and structure		assigned the responsibility of monitoring safety of medicines?						
					Is there a clear mandate and organizational structure for the pharmacovigilance center? *Request documentation to verify.*	No	Presence of clear mandate & organizational structure for PV centre				
					What is the organizational affiliation of the PV Center/Unit? (e.g., University, hospital pharmacy department, NMRA etc.)	NMRA					
			The pharmacovigilance center has designated, qualified	Annual	How many staff members (full-time equivalent) does the PV center have who are specifically	5	15	Staff establishment	CEO, PPB	Annual PPB Report	Long Term

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			human resources to carry-out its functions		responsible for carrying out its functions (technical and administrative)? Request documentation to verify.						
					Do the technical staff in the pharmacovigilance center have professional or educational qualifications related to medicine, pharmacy/pharmaceutical, or related field (e.g. epidemiology, public health)?	Yes	Staff with B. Pharm qualifications				
2.3	C	S	Existence of a dedicated financial provision or statutory budget for the pharmacovi	Annual	Is there an annual budgetary allocation for pharmacovigilance activities or for the Pharmacovigilance Center?	Yes	Availability of budget allocation	PPB Budget	CEO, PPB	Annual PPB Report	

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			gilance center		In the last fiscal year, how much funds were allocated by the MOH and donors for pharmacovigilance activities? *Please enter the amount in the Answer box and specify the currency in the Notes column. Request documentation to verify.*	Funds allocated					
2.4	C	S	Existence of a functional national medicine safety advisory committee	Annual	Does a national medicine safety advisory committee exist with the responsibility to provide technical advice on the safety of medicines to the regulatory authority?	Yes	Presence of national medicine safety advisory committees	PERAC/NVSAC reports	PPB Secretariat	Quarterly PERAC reports/NVSAC reports	

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
					Has the national medicine safety advisory committee met at least twice in the previous 12 months? *Request documentation to verify.*		2				
			Existence of updated national pharmacovigilance guidelines developed or reviewed within the past 5 years	3 years	Does a national guideline for pharmacovigilance (or a related document) exist?	Yes	Availability of national PV guidelines	Guidelines on the Safety and Vigilance of Medical Products and Health technologies Guidelines for Establishment of the QPPV Guidelines for Monitoring Reporting and Managing AEFI in Kenya Guidelines on the Safety and Vigilance of Medical Products and	CEO, PPB	Guideline review workshop report	Long Term
					Has the national pharmacovigilance guideline been developed or reviewed within the past 5 years?	No	Availability of reviewed national PV guidelines				
					When were the guidelines last reviewed? *Request documentation to verify.*	2019	Guidelines reviewed every 5 years				

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
								Health Technologies			
2.6	C	S	Existence of updated standard operating procedures (SOPs) for conducting pharmacovigilance activities	Annual	Does PPB have SOPs for pharmacovigilance activities?	Yes	Availability of SOPs for PV activities	PV SOPs	CEO, PPB	SOPs development/review reports	Long Term
					How many SOPs for pharmacovigilance activities exist?	2					
					How many SOPs for pharmacovigilance activities are updated?	0	All available SOPs updated				
					When were the SOPs last reviewed? *Request documentation to verify.*	2016	SOPs to be reviewed every 3 years				
2.7	C	S	Existence of a mechanism to disseminate pharmacovi	Annual	Is there a mechanism in place to disseminate	Yes	Presence of mechanism to disseminate	Quarterly Bulletin Annual newsletter Website - Realtime	Head, VMS	Quarterly Progress reports	

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			gilance information (including one or more of the following: newsletters, information bulletin, website or phone line for dissemination of pharmacovigilance information)		Is there a newsletter or information bulletin for dissemination of PV information? *Request documentation to verify.*	Yes	Availability of newsletter				
					Is there a website for dissemination of PV information?	Yes	Availabilty of Website				
					Is there a publicly advertised phone line to receive and provide medicine safety and PV information?	Yes	Availability of publicly advertised phone				
					Is there another mechanism for dissemination of PV information? *Please describe the mechanism in Notes*	Yes					
2.8	C	S	Existence of harmonized national	3 years	Is PV incorporated into the national pre-	No	Incorporation of	National pre service PV curriculum	CEO, PPB		Long Term

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			pharmacovigilance curricula for key healthcare workers - Pre-Service		service curricula of doctors? *Request documentation to verify.*		National pre-service curricula for doctors, nurses and pharmacists				
					Is PV incorporated into the national pre-service curricula of nurses? *Request documentation to verify.*	No					
					Is PV incorporated into the national pre-service curricula of pharmacists? *Request documentation to verify.*	Yes					
					Is the curriculum in use for pre-service training of healthcare workers the EAC harmonized PV curriculum? *Request documentation to verify.*	No	Incorporation of National pre-service curricula for healthcare				

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
							workers				
2.9	C	S	Existence of harmonized pharmacovigilance curricula for key healthcare workers - In-Service	3 years	Is there a pharmacovigilance training module, manual, or curriculum for in-service training of health care workers? *Request documentation to verify.*	Yes	Availability of PV training module for in-service training	1-day curriculum 3-day curriculum 5-day curriculum	Head VMS	Training report	Long term
					Is the curriculum in use for in-service training of healthcare workers the national harmonized PV curriculum? *Request documentation to verify.*	No	Harmonized PV curriculum				
2.10	C	P	Number of healthcare workers trained in pharmacovigilance in	Quarterly	How many healthcare workers has the center/program trained on PV in the previous 12			Training reports	Head, VMS	Quarterly progress reports	Long Term

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			the previous 3 months through in-service training program		months (through in-service training)? -- *Request documentation to verify.*						
					How many training events/sessions were conducted in the previous 12 months? -- *Request documentation to verify.*	3					
2.11	C	S	Existence of a functioning platform, mechanism or strategy for the coordination of pharmacovigilance activities - National Level	Annual	Does a platform, mechanism or strategy for the coordination of pharmacovigilance activities (such as PV technical working group, forum or regularly scheduled meetings) exist among national stakeholders?	Yes	Existence of PV TWG	TORs for the TWG	Head, VMS	Quarterly progress reports / minutes	

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
					Have the key national stakeholders been convened at least once in the previous 12 months? *Request documentation to verify.*	No	1				
2.12	S	P	Evidence of consideration of safety data when developing and updating standard treatment guidelines	3 years	Are pharmacovigilance data considered when developing standard treatment guidelines? *Request documentation to verify.*	Yes	Incorporation of safety data in STG development	STGs	Chair, NMTC	STG development report	
2.13	C	S	National pharmacovigilance center is a full or associate member of the WHO Program for International Drug Monitoring	Annual	Is the national pharmacovigilance center a full or associate member of the WHO Program for International Drug Monitoring?	Yes	Membership to WHO program for IDM	Certificate of Membership/ Annual subscription	Head, VMS	Annual report	

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
Component 3. Signal Generation and Data Management											
3.1	C	S	Existence of a national database for pharmacovigilance information	Annual	Does a central database exist for managing PV data?	Yes	Existence of database for PV data	PV database	Head, VMS	PV Reports	
					Does the central database contain data from various PV sources and methods? *Request documentation to verify.*	Yes	Yes				
3.2	C	P	Evidence of a process or mechanism for sharing information with other regulatory functions, other regulatory agencies and global databases	Annual	Has information in the database been shared (either electronically or via report) with other regulatory functions, other regulatory agencies and/or global databases? *Request documentation to verify.*	Yes	Existence of systems for sharing information in PV database	Emails/Letters/Submission of data to Vigilyze	Head, VMS	Annual reports	
3.3	C	S	Existence of a standard adverse	Annual	Is there a standard AE reporting form?	Yes	Existence of	SADR reporting form	Head, VMS	Annual reports	

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			event (AE) reporting form Subset indicators: The standard reporting form, or separate forms, provide for reporting of— - Adverse drug reactions - Suspected medication errors - Therapeutic ineffectiveness - Suspected misuse, abuse of and/or dependence on		*Request documentation to verify.*		relevant forms	AEFI reporting form Medication error reporting form Adverse transfusion reaction form Medical device incident reporting form PQMP forms			
					Are there relevant fields in the standard AE form (or a separate form) to report adverse drug reactions?	Yes					
					Are there relevant fields in the standard AE form (or a separate form) to report suspected medication errors?	Yes					
					Are there relevant fields in the standard AE form (or a separate form) to report therapeutic ineffectiveness?	Yes					
					Are there relevant fields in the standard AE form (or a separate form) to report suspected	Yes					

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			medicines '- Adverse events following immunization (AEFI) - Medical devices and diagnostics		misuse, abuse and/or dependence on medicines?						
					Are there relevant fields in the standard AE						
					form (or a separate form) to report AEFIs?	Yes					
					Are there relevant fields in the standard AE form (or a separate form) to report adverse events related to medical devices and diagnostics?	Yes					
3.4	C	S	Existence of a form (or section of ADE form) for reporting suspected product quality issues	Annual	Is there a form with relevant fields for reporting suspected/ observed poor quality issues? *Request documentation to verify.*	Yes	Existence of form for reporting suspected product quality issues	PQMP reporting form	Head, VMS	Annual reports	

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
3.5	S	S	Existence of a form or mechanism for the public to report AEs (Patient reporting system)	Annual	Is there a standard reporting form for the general public to report AEs?	Yes	Existence of a form or mechanism for the public to report AEs	PV reporting tool - SADR, AEFI, medication error, medical devices	Head, VMS	Annual reports	
3.6	S	S	Existence of electronic AE reporting system that complies with international reporting format standards	3 years	Is there an electronic AE reporting system? Is the system compliant with the international reporting standards (E2B)?	Yes	Existence of electronic AE	Electronic AE reporting system (PvERS)	Head, VMS	Annual reports	
Component 4. Risk Assessment and Evaluation											
4.1	C	P	Total number of AE reports received in the previous 12 months (also	Annual	What is the total number of AE reports received in the previous 12 months? *Request documentation to verify.*			Electronic AE reporting system (PvERS)	Head, VMS	Annual reports	Immediate

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			expressed as number of AEs per 100 000 persons in the population) Sub-indicators: - ADR - Suspected medication errors - Therapeutic ineffectiveness - Suspected misuse, abuse, dependence - AEFI - AE related to medical devices and diagnostics		Of the total, what is the number of reports of ADR?						
					Of the total, what is the number of reports of suspected medication errors?						
					Of the total, what is the number of reports of therapeutic ineffectiveness?						
					Of the total, what is the number of reports of suspected misuse, abuse, dependence?						
					Of the total, what is the number of reports of AEFI?						
					Of the total, what is the number of reports of AE related to medical devices and diagnostics?						

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
					What is the total population of the country?						
4.2	C	P	Number and percentage of total AE reports received by the national pharmacovigilance center in the previous 12 months from: - Marketing Authorization Holders - PHPs - Health care providers - Patients	Annual	What is the number of AE reports received by the national pharmacovigilance center in the previous 12 months from marketing authorization holders?			Electronic AE reporting system (PvERS)	Head, VMS	Annual reports	Immediate
					What is the number of AE reports received by the national pharmacovigilance center in the previous 12 months from public health programs?						
					What is the number of AE reports received by the national pharmacovigilance center in the previous 12						

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
					months from healthcare providers?						
					What is the number of AE reports received by the national pharmacovigilance center in the previous 12 months from patients?						
					What is the total number of AE reports received in the previous 12 months?						
4.3	C	P	Number and percentage of total AE reports received that are entered in the national database in the previous 12 months	Annual	What is the total number of ADE reports received that have been entered in the national database in the previous 12 months?			Electronic AE reporting system (PvERS)	Head, VMS	Annual reports	Immediate
					What is the total number of ADE reports received in the previous 12 months?						

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
4.5	C	P	Number and percentage of total AE reports acknowledged and/or issued feedback in the previous 12 months	Annual	What is the total number of AE reports acknowledged/issued feedback in the previous 12 months?			Electronic AE reporting system (PvERS)	Head, VMS	Annual reports	Immediate
					What is the total number of AE reports received in the previous 12 months?						
4.6	C	P	Number and percentage of ADE reports subjected to causality assessment in the previous 12 months	Annual	What is the total number of AE reports subjected to causality assessment in the previous 12 months?			Electronic AE reporting system (PvERS)	Head, VMS	Annual reports	Immediate
					What is the total number of ADE reports received in the previous 12 months?						
4.7	C	P	Number and percentage of ADE reports committed to VigiBase	Annual	How many of the ADE reports received at the national pharmacovigilance center were committed to			Electronic AE reporting system (PvERS); VigiBase	Head, VMS	Annual reports	Immediate

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			in the previous 12 months		Vigibase in the previous 12 months?						
					What is the total number of ADE reports received in the previous 12 months?						
4.8	C	P	Average completeness score of quarterly reports committed to VigiBase in the previous four quarters (= one year)	Annual	What was the average completeness score of quarterly reports committed to Vigibase in the previous four quarters? *Consult quarterly reports from VigiGrade for completeness scores of submitted reports*		100%	VigiBase	Head, VMS	Annual reports	Immediate
4.9	C		Number of active surveillance activities initiated,	Annual	How many active surveillance studies have been conducted in the last 12 months?			Active surveillance protocols and reports	Head, VMS	Annual reports	Immediate

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			ongoing or completed during the previous 12 months		Indicate what type (e.g. cohort event monitoring, targeted spontaneous reporting, etc.) and stage of completion (e.g. initiated, on-going or completed) for each study. *Request documentation to verify.*			PV active surveillance implementation plan			
4.1	S	P	Number and percentage of total AE reports received at the national pharmacovigilance center in the previous 12 months from healthcare providers by	Annual	What is the number of AE reports received in the previous 12 months submitted by doctors?				Head, VMS	Annual reports	Immediate
					What is the number of AE reports received in the previous 12 months submitted by nurses?						
					What is the number of AE						

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			type of provider		reports received in the previous 12 months submitted by pharmacists?						
					What is the total number of AE reports received in the previous 12 months?						
4.11	S	P	Evidence of supervision visits to marketing authorization holders by NMRA that address PV	Annual	Does the NMRA conduct supervision visits of MAHs that address PV?			PV Assessment reports PV inspection report	Head, VMS	Annual reports	Short Term
					How many supervision visits have been conducted in the previous 12 months?						
Component 5. Risk Management and Communication											
5.1	C	O	Number of regulatory actions taken in the previous 12 months as a consequence of national pharmacovi	Annual	How many regulatory actions were taken in the preceding 12 months as a consequence of pharmacovigilance activities that			Email/Bulletin/Website	Head, VMS	Annual Report	Immediate

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			gilance activities including: - Number of product label changes (variation); - Number of safety warnings on medicines to health professionals and general public; - Number of withdrawals of medicines; - Number of other restrictions on use of medicines; - Number of treatment guideline/policy changes		resulted in *product label changes (variation)*?						
					How many regulatory actions were taken in the preceding 12 months as a consequence of pharmacovigilance activities that resulted in *safety warnings on medicines to health professionals*?						
					How many regulatory actions were taken in the preceding 12 months as a consequence of pharmacovigilance activities that resulted in safety warnings on medicines to the general public?						

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			Request documentation to verify.		How many regulatory actions were taken in the preceding 12 months as a consequence of pharmacovigilance activities that resulted in withdrawals of medicines?						
					How many regulatory actions were taken in the preceding 12 months as a consequence of pharmacovigilance activities that resulted in *treatment guideline/policy changes*?						
					How many regulatory actions were taken in the preceding 12 months as a						

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
					consequence of pharmacovigilance activities that resulted in *other restrictions on use of medicines*?						
5.2	C	O	Number of signals detected in the past 3 years by the pharmacovigilance center	3 years	How many signals were detected in the past 3 years by the pharmacovigilance center?			Signal Register/Communication	Head, VMS	Annual Report	Immediate
5.3	S	O	Average time lag between identification of safety signal of a serious ADR or significant medicine safety issue generated nationally and communication to health care	Annual	How long does it take from when a safety signal or significant safety issue is identified to when it is communicated to health workers and the public? Please answer in days.		30 days	Signal report/ Communication to health care workers	Head, MS	Annual Report	Immediate

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			workers and the public								
5.4	S	O	Number of suspected product quality issues detected through the pharmacovigilance system	Annual	What is the number of suspected product quality issues detected through the pharmacovigilance system in the previous 12 months? Request documentation to verify.			PvERS/PMS Database	Head, VMS	Annual Report	Immediate
5.5	S	O	Percentage of planned issues of the medicine safety bulletin (or any other health-related newsletter that routinely features ADR or medicine	Annual	How many issues of the medicine safety bulletin are supposed to be published per year?		4 (Quarterly)	Published Bulletin	Head, VMS	Annual Report	Immediate
					How many issues of the medicine safety bulletin were published in the previous 12 months? *Request documentation to verify.*						

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			safety issues) published in the previous 12 months								
5.6	S	O	Number of products voluntarily withdrawn by marketing authorization holders because of safety concerns in the previous 12 months	Annual	How many products were voluntarily withdrawn by marketing authorization holders because of safety concerns in the previous 12 months?			Database of reported safety concerns	Director, HPT	Annual Report	Immediate
5.7	S	O	Number and percentage of medicine safety information requests addressed in the previous 12 months	Annual	How many requests for information about medicine safety were received in the previous 12 months? Request documentation to verify.			Vigilyze/Uppsala Reports/Communication from other regulators	Head, VMS	Annual Report	Immediate
					Of the total received, how						

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
					many requests for medicine safety information were addressed in the previous 12 months?						
5.8	S	O	Number of medicine safety issues of local relevance identified from outside sources (e.g., from another country, from EAC region or international sources) and acted on locally in the previous 12 months	Annual	How many medicine safety issues identified from outside sources were acted on locally in the previous 12 months? *Request documentation to verify.*			Safety communication	Head, VMS	Annual Report	Immediate
5.9	S	O	Number of public or community education	Annual	How many public or community education activities relating			Reports of the Community activities/Tal	Head, VMS	Annual Report	Immediate

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Questions	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
			activities relating to medicine safety carried out in the previous 12 months		to medicine safety were carried out in the previous 12 months? *Request documentation to verify.*			kshows/Social Media			

b) Public Health Programs

Key: *Immediate(0-6months), Short Term (6-12 months), Long Term (More than 1 year)*

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
Component 2. Systems, Structures, and Stakeholder Coordination											
P2.1	C	P	Pharmacovigilance activities included within the strategic and/or annual operational plans of public health programs	Annual	Are pharmacovigilance activities included within the strategic and/or annual operational plans of public health programs? *Request documentation to verify.*	3	9	Strategic and/ or Annual operational plans	Head, PHP	Annual	Long Term
P2.2	C	S	Existence of a dedicated financial provision or statutory budget for the PHPs	Annual	Is there an annual budgetary allocation for pharmacovigilance activities for the PHP? *Request documentation to verify.*	3	9	PHP Budget	Head, PHP	Annual	Long Term
					In the last fiscal year, how many funds were allocated by the MOH and donors for pharmacovigilance activities? *Please enter the amount in the Answer box and specify the currency in the Notes column.*		9				
P2.3	C	S	Existence of a mechanism to disseminate pharmacovigilance information (including	Annual	Is there a mechanism in place to disseminate PV information	3	9	Presence of bulletins, Newslett	Head, PHP	Annual report	Long Term
					Is there a newsletter or information bulletin for dissemination of PV	3	9				

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
			one or more of the following: newsletters, information bulletin, website or phone line for dissemination of pharmacovigilance information)		information? *Request documentation to verify.*			ers, Website			
					Is there a website for dissemination of PV information?	3	9				
					Is there a publicly advertised phone line to receive and provide medicine safety and PV information?	1	9				
					Is there another mechanism for dissemination of PV information? *Please describe the mechanism*	3	9				
P2.4	C	P	Number of healthcare workers trained in pharmacovigilance in the previous 12 months through in-service training	Annual	How many healthcare workers has the center/program trained on PV in the previous 12 months (through in-service training)? *Request documentation to verify.*			Training reports	PHP PV/PMS focal person	Annual report	Short Term
					How many training events/sessions were conducted in the previous 12 months? *Request documentation to verify.*						
P2.5	C	P	Number of national treatment guidelines or protocols in use within the public health programs that consider pharmacovigilance	Annual	Do the treatment guidelines or protocols in use in the PHP provide instruction for PV activities? *Request documentation to verify.*	2	9	Treatment guidelines or protocols	PHP PV/PMS focal person	Annual report	Long Term

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
P2.6	S	P	Evidence of consideration of safety data when developing and updating standard treatment guidelines or treatment policies	3 years	Is pharmacovigilance data considered when developing standard treatment guidelines? *Request documentation to verify.*	1	9	Standard Treatment Guidelines or Policies	PHP PV/PMS focal person	Annual report	Long Term
Component 3. Signal Generation and Data Management											
P3.1	C	P	PHPs use the national, standard ADR/AE reporting form	Annual	Does the PHP use the national, standard ADR/AE reporting form?	3	9	ADR/AE reports from PHP	PHP PV/PMS focal person	Annual report	Immediate
Component 4. Risk Assessment and Evaluation											
P4.1	C	P	Number and percentage of ADR/AE reports received by PHPs that were submitted to the national pharmacovigilance center in the previous 12 months	Annual	What is the number of AE reports received by the PHP in the previous 12 months? What is the number of AE reports submitted by the PHP to the national PV center in the previous year?			ADR/AE Reports	PHP PV/PMS focal person	Quarterly Report	Immediate
P4.2	C	P	Number of active surveillance activities initiated, ongoing or completed during the past three years	3 years	How many active surveillance studies have been conducted in the last three years (36 months)? Indicate what type (e.g. cohort event monitoring, targeted spontaneous reporting, etc.) and stage of completion (e.g. initiated, on-going or	TBD		Study Protocol Progress report	PHP PV/PMS focal person	Annual report	Immediate

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
					completed) for each study. Request documentation to verify						
P4.3	S	O	Percentage of patients in public health programs for whom drug-related, serious unexpected adverse events were reported in the previous 12 months	Annual	What is the total number of patients receiving medicines under the PHP? *Request documentation to verify.*			SADR/AE Reports	PHP PV/PMS focal person	Annual report	Immediate
					What is the total number of patients receiving medicines in the PHP who experienced drug-related, serious, unexpected adverse events? Request documentation to verify.						
Component 5. Risk Management and Communication											
P5.1	S	O	Average time lag between identification of safety signal of a serious ADR or significant medicine safety issue generated nationally and communication to health care workers and the public	Annual	How long does it take from when a safety signal or significant safety issue is identified to when it is communicated to health workers and the public? *Please enter your answer in days.*		TBD	Supervision reports	PHP PV/PMS focal person	Annual Report	Immediate
P5.2	S	O	Number of suspected product quality issues detected through public health programs	Annual	What is the number of suspected product quality issues detected through the PHP in the previous 12 months?			PQMP Report	PHP PV/PMS focal person	Quarterly Report	Immediate

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
P5.3	S	O	Existence of a program-related newsletter that routinely features ADR or medicine safety information	Annual	Is there a program-related newsletter, bulletin or other publication that routinely features ADR or medicine safety information?	2	9	Newletter, bullettin or publication	PHP PV/PMS focal person	Quarterly Report	Long Term
P5.4	S	O	Number and percentage of medicine safety information requests addressed in the previous 12 months	Annual	How many requests for information about medicine safety were received in the previous 12 months? *Request documentation to verify.*			Medicines safety reports	PV/PMS focal person	Quarterly Report	Short Term
					How many requests for medicine safety information were addressed in the previous 12 months? Request documentation to verify.						
P5.5	S	O	Number of medicine safety issues of local relevance identified from outside sources and forwarded to NMRA/PV Centre in the previous 12 months	Annual	How many medicine safety issues identified from outside sources were acted on locally in the previous 12 months? *Request documentation to verify.*				PV/PMS focal person	Quarterly Report	Immediate
P5.6	S	O	Number of public or community education activities relating to medicine safety carried out in the previous 12 months	Annual	How many public or community education activities relating to medicine safety were carried out by the PHP in the previous 12 months? *Request documentation to verify.*			Activity Report	PV/PMS focal person	Quarterly Report	Short Term

c) Health Facilities

Key: *Immediate(0-6months), Short Term (6-12 months), Long Term (More than 1 year)*

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
Component 2. Systems, Structures, and Stakeholder Coordination											
F2.	C	S	Existence of a mechanism to disseminate pharmacovigilance information (including one or more of the following: newsletters, information bulletin, website or phone line for dissemination of pharmacovigilance information)	Annual	Is there a mechanism in place to disseminate PV information in your health facility?		Availability of mechanism for dissemination of PV information	Memos, Bulletins	Facility CEO/Med Supt.	Quarterly PV reports	Immediate
					Is there a newsletter or information bulletin for dissemination of PV information? *Request documentation to verify.*						
					Is there a website for dissemination of PV information?						
					Is there a publicly advertised phone line to receive and provide medicine safety and PV information?						
					Is there another mechanism for dissemination of PV information? *Please describe the mechanism in Notes*						

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
F2.2	C	P	Number of healthcare workers trained in pharmacovigilance in the previous 12 months through in-service training	Annual	How many healthcare workers has the facility trained on PV in the previous 12 months (through in-service training)? *Request documentation to verify.*			Training Reports	PV focal person	Quarterly PV reports	Immediate
					How many training events/sessions were conducted in the previous 12 months? *Request documentation to verify.*						
Component 3. Signal Generation and Data Management											
F3.	S	P	Percentage of surveyed healthcare facilities with functional pharmacovigilance (submitted >10 ADE reports to the national pharmacovigilance center in the previous 12 months)	Annual	How many AE reports did the health facility submit to the national pharmacovigilance center in the previous 12 months?			PvERs	PV focal person	Quarterly PV reports	Immediate
			Facility level: Healthcare facility submitted >10 AE reports to the national pharmacovigilance center in the previous 12 months)								
Component 4. Risk Assessment and Evaluation											
Component 5. Risk Management and Communication											

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
F5.1	S	O	Percentage of surveyed hospitals that have Medicines and Therapeutics Committees that have carried out pharmacovigilance activities or addressed medicine safety issues in the previous 12 months	Annual	Does the health facility have a Medicines and Therapeutics Committee?		Availability of MTC in assessed facilities	NMTC Reports	Chairman NMTC	Quarterly PV reports	Long Term
					Within the previous 12 months, has the MTC carried out any pharmacovigilance activities or addressed medicine safety issues? *Request documentation to verify.*		4-6 meeting				
F5.2	S	O	Number of suspected product quality issues detected through surveyed health facilities	Annual	What is the number of suspected product quality issues detected at the health facility e in the previous 12 months?			PvERs	PV focal person	Quarterly PV reports	Immediate
F5.3	S	O	Number and percentage of medicine safety information requests addressed in the previous 12 months	Annual	How many requests for information about medicine safety were received in the previous 12 months? *Request documentation to verify.*				PV focal person	Quarterly PV reports	Long Term
					How many requests for medicine safety information were addressed in the previous 12 months?						

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
					Request documentation to verify.						
F5. 4	S	O	Number of public or community education activities relating to medicine safety carried out in the previous 12 months	Annual	How many public or community education activities relating to medicine safety were carried out by the health facility in the previous 12 months?			Health Talks Schedule	Pharmacist I/C/PV focal person	Quarterly PV reports	Immediate

d) Marketing Authorization Holders

Key: *Immediate(0-6months), Short Term (6-12 months), Long Term (More than 1 year)*

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
Component 1. Policy, Law, and Regulation											
Component 2. Systems, Structures, and Stakeholder Coordination											
M2.1	S	S	Percentage of surveyed marketing authorization holders that have a designated qualified (QPV) pharmacovigilance person (MAH: Existence of a qualified pharmacovigilance person at the MAH)	Annual	Is there a designated qualified pharmacovigilance person (QPV) at the company? *Request documentation to verify.*		100%	PPB database	Company CEO/Head	Annual Report	Immediate
Component 3. Signal Generation and Data Management											
Component 4. Risk Assessment and Evaluation											
M4.1	S	S	Percentage of surveyed marketing authorization holders that have procedures for the collection and reporting of safety issues (e.g. ICSRs and PSURs) to the NMRA	Annual	Does the marketing authorization holder have procedures in place for collecting and reporting safety issues to the NMRA? *Request documentation to verify*		100%	PPB inspection reports	QPPV	Annual reports	Immediate
Component 5. Risk Management and Communication											
M5.1	S	O	Number and percentage of risk mitigation plans currently in place that	Annual	Does the MAH have any risk mitigation plans currently in place for high-risk medicines?		Availability of RMP	PPB inspection	QPPV	Annual reports	Immediate

Indicator #	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting	Timeline
			are targeted at high-risk medicines that have been submitted to the NMRA				for high risk medicines	reports			
					How many risk mitigation plans are in place?						
					How many risk mitigation plans have been submitted to the NMRA?						

REPUBLIC OF KENYA

Ministry of Health

PHARMACY AND POISONS BOARD

P. O. Box 27663 - 00506 Lenana Road Opposite Russian Embassy, Nairobi
Tel: +254 709 770 100, +254 795 734 049
Website: www.pharmacyboardkenya.org
Email: info@pharmacyboardkenya.org, pv@pharmacyboardkenya.org