HPT/PDS/VMS/GUD/086
Revision No.0

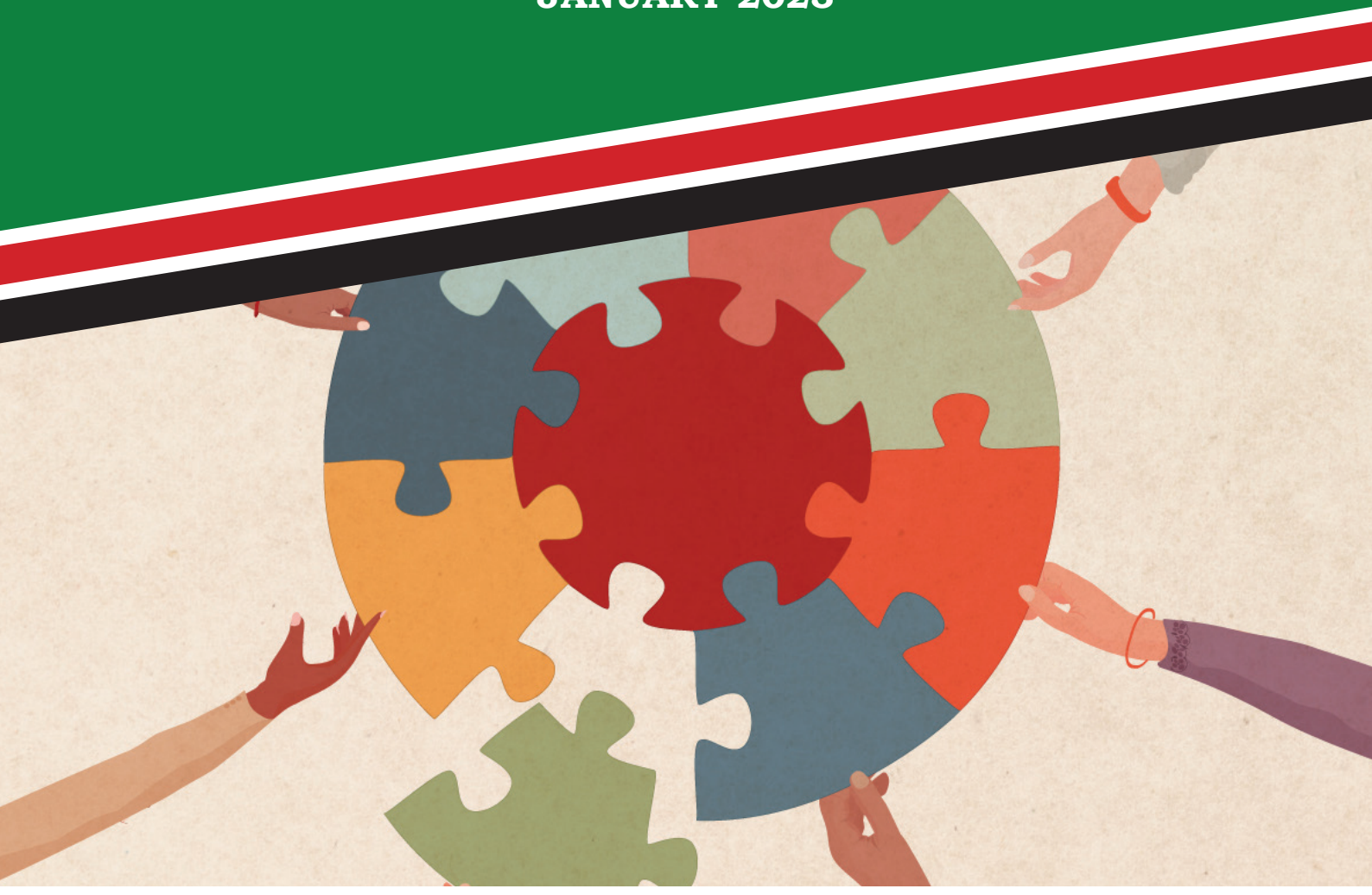
REPUBLIC OF KENYA

Ministry of Health

PHARMACY AND POISONS BOARD

COLLABORATION STRATEGY BETWEEN PHARMACY AND POISONS BOARD AND PUBLIC HEALTH PROGRAMS

JANUARY 2023



Citation

The author of this guideline is the Pharmacy and Poisons Board, a State Corporation under the Ministry of Health, Republic of Kenya. It may be reproduced or adopted on condition that the recommended citation below is made.

Recommended Citation

Republic of Kenya, Ministry of Health, Pharmacy and Poisons Board, Collaboration Strategy between Pharmacy and Poisons Board and Public Health Programs, Revision 0, 2023.

Pharmacy and Poisons Board, 2023

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/086	**Collaboration Strategy Between Pharmacy and Poisons Board and Public Health Programs**	**Revision No:0**	**Effective date:** 23/01/2023 **Review date:** 01/01/2028

Prepared by Principal Regulatory Officer

Name..... Dr Nambwa Pamela

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

Table Of Contents

Abbreviations and Acronyms

ADR	Adverse Drug Reaction
AE	Adverse events
AEFI	Adverse events following immunization.
COVID-19	Coronavirus Disease 2019 (COVID-19)
DNMP	Division of National Malaria Program (DNMP)
DRMH	Division of Reproductive and maternal Health (DRMH)
ICSR	Individual Case Safety Reports
KHIS	Kenya Health Information system
KT&TA	Kenya Tissue and Transplant Authority (KT&TA)
LF	Lymaphatic Filariasis
MDA	Mass Drug Administration
mPvERS	mobile Pharmacovigilance Electronic Reporting System
MTaPS	Medicines, Technologies and Pharmaceutical Services Program
NASCOP	National AIDS & STI Control Program (NASCOP)
NCAH	Division of Neonatal, Child and Adolescent Health Unit
NCD	Division of Non Communicable Diseases
NLTP	National Tuberculosis, Leprosy and Lung Disease Program (NLTP)
NRA	National Regulatory Authority
NTD	Neglected Tropical Diseases Unit (NTD)
NVIP	National Vaccines & Immunization Program (NVIP)
PDS	Product Safety Department
PHP	Public Health Programs
PMS	Post Market Surveillance
PPB	Pharmacy and Poisons Board
PV	Pharmacovigilance
PvERS	Pharmacovigilance Electronic Reporting System
QMS	Quality Management Services

Glossary of terms

The following definitions describe terminologies in the context of this guideline.

Active surveillance - Active measures are taken to detect adverse events. It involves active follow-up after treatment where the events may be detected by asking patients directly or screening patient records. It is best done prospectively. Active pharmacovigilance is sometimes very descriptively referred to as, "hot pursuit"

Adverse Event/ Adverse Experience - Any untoward medical occurrence that may present during treatment with a pharmaceutical product but which does not necessarily have a causal relationship with this treatment.

Adverse event following immunization (AEFI) - Any untoward medical occurrence which, follows **i**mmunization and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

Adverse Drug Reaction - A response to a drug which is noxious and unintended, and which occurs at doses normally used in humans for the prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function. An adverse drug reaction, in contrast to an adverse event, is characterized by the fact that a causal relationship between a medical product and an occurrence is suspected.

Board - The Pharmacy and Poisons Board

Cohort Event Monitoring (CEM) - A prospective, observational, cohort study of adverse events associated with one or more medicines

Collaboration - A working practice whereby individuals work together for a common purpose to achieve specific benefits. This shall be between the Board and other public health programs. Collaboration can help to enhance program capacity and build confidence in the public.

Clinical Trial - A systematic study on pharmaceutical or medical products in human subjects (including patients and other volunteers) in order to discover or verify the effects of and/or identify any adverse reaction to investigational products, and/or to study the absorption, distribution, metabolism and excretion of the products with the objective of ascertaining their efficacy and safety. Clinical trials are generally classified into Phases: I to IV. Phase IV

trials are studies performed during the marketing of the pharmaceutical/medical product. They are carried out on the basis of the product characteristics for which the marketing authorization was granted and are normally in the form of post-marketing surveillance.

Drug - In this context also known as medicine or medical products.

Healthcare providers/professionals – In the context of this guideline, include medical doctors, dentists, pharmacists, clinical officers, pharmaceutical technologists, nurses, community health workers and medical laboratories staff.

Health technology - Also known as medical device including in vitro diagnostics

Herbal medicines - Include herbs, herbal materials, herbal preparations and finished herbal products, that contain as active ingredients parts of plants, or other plant materials, or combinations.

Individual case safety report (ICSR) – Also known as a suspected adverse drug reaction report containing information on the patient, drug reaction, suspected drug/medicine/vaccine/medical device and the reporter.

Manufacturer - A person or a body who sells a product under their own name, or under a trademark, design, trade name or other name or mark owned or controlled by the person or the body, and who is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the product, or for assigning to it a purpose, whether those tasks are performed by that person or on their behalf.

Medical Device - Any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

a. Diagnosis, prevention, monitoring, treatment or alleviation of disease;
b. Diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
c. Investigation, replacement, modification or support of the anatomy or of a physiological process;
d. Supporting or sustaining life;
e. Control of conception;
f. Disinfection of medical devices;

g. Providing information by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Medication error - An unintended failure in the drug treatment process that leads to, or has the potential to lead to harm to the patient.

National Pharmacovigilance Centre - A single, government-recognized centre (or integrated system) within a country with the clinical and scientific expertise to collect, collate, analyze and give advice on all information related to drug safety.

Pharmaceutical industry- Refers to the manufacturers, marketing authorization holders, local technical representatives, distributors, parallel importers

Pharmacoepidemiology - The study of the use and effects of drugs in large numbers of people.

Pharmacovigilance - The science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem. Also known as Vigilance to include blood and blood products and health technologies.

Public Health Program - Means any program offering any kind of health services that is created by the governmental entity.

Risk-Benefit Balance - An evaluation of the positive therapeutic effects of the medical product in relation to the risks (any risk relating to the quality, safety or efficacy of the medical product as regards patients' health or public health.

Safety concern – An identified risk, important potential risk or missing information (refer to their respective definitions above)

Signal - Reported information on a possible causal relationship between an adverse event and a drug, the relationship being unknown or incompletely documented previously. Usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the event and the quality of the information.

Unexpected Adverse Reaction - An adverse reaction, the nature or severity of which is not consistent with domestic labelling or market authorization, or expected from characteristics of the drug.

Acknowledgement

The Pharmacy and Poisons Board acknowledges the contribution of the following in the research and compilation of this strategy from the Ministry of Health, our stakeholders and Partners.

We take this early opportunity to thank all the colleagues from Public Health Programs for their technical input and USAID-MTaPS for both technical and financial support.

Foreword

The significant benefits of Health Products and Technologies (HPTs) in the reduction of morbidity and mortality cannot be over-emphasized, however, they have the potential of causing harm despite utmost care when administering them. The Pharmacy and Poisons Board continuously implements strategies aimed at ensuring the safety, quality, and efficacy of HPTs. The safety, quality, and efficacy of surveillance of HPTs within Public Health Programs(PHPs) are key as they are based on the direct administration of HPTs for the prophylaxis, treatment, or control of diseases.

Pharmaceutical industries contribute to access to HPTs. This is done either through donations or the provision of HPTs at reduced costs through access programs for direct administration to large communities through PHPs. Patients from affected communities are often not directly engaged in the decision-making process with PHPs, whose decisions can positively or adversely affect the implementation of the interventions. Various factors are documented that influence compliance to MDA in the elimination of LF including lack of awareness on the benefits of the medicines given during MDA, the introduction of new and more effective medicines, the increase in the number of tablets to be swallowed, and adverse events that occur after taking the medicines. It is therefore both the PHPs and NRAs work collaboratively to provide factual and real-time information to the concerned communities.

The success of PHPs is indeed dependent on the active collaboration with other stakeholders including the patients and NRAs.This document outlines the need and importance of integrating pharmacovigilance as a key component in public health programs (PHPs) that use health products and technologies. Additionally, it describes the importance of collaborations between the Pharmacy and Poisons Board (PPB) to strengthen the safety monitoring of Health Products and Technologies within the various PHPs.

Dr Fred M.Siyoi
Chief Executive Officer

Preface

The Pharmacy and Poisons Board (PPB) is the National Regulatory Authority mandated by CAP 244 of the Laws of Kenya, to regulate the practice of Pharmacy in Kenya and the manufacture and trade of drugs and poisons.

The main objective of this strategy is to promote and strengthen the pharmacovigilance and post-marketing surveillance systems within the public health programs in Kenya. This strategy aims to assure the safety, quality, and efficacy of health products and technologies by ensuring a timely collaborative exchange of information on safety and quality-related issues. The strategy shall be used alongside other existing national pharmacovigilance and post-market surveillance guidelines and legal frameworks.

Dr Ahmed Mohammed
Director Health Products and Technologies

Executive Summary

Pharmacovigilance (PV) is defined by WHO as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other possible drug-related problems." PV is a critical component of patient care that aims at making the best use of health products for the treatment and prophylaxis of diseases in order to minimize harm to patients. An effective PV system supports the identification of risks and risk factors within the shortest time possible to allow minimization of harm. Effective communication of this information is vital in promoting evidence-based uses of HPTs and prevention of adverse events while ensuring optimal therapeutic interventions. Acceptance of public health interventions by patients and clients is dependent on effective communication on the use of HPTs and any potential harms that may arise and how to mitigate the same.

It is documented that significant harm to a few patients can adversely impact the implementation of public health interventions due to rumors and myths about adverse events coupled with the absence of data supporting the safety of the HPTs. PV plays a critical function in the generation of this data and information, on other HPTs related problems including potential therapeutic failure, medication errors, quality defects, interactions between medicines, food medicines interactions, and in appropriate HPT use. The evidence around these problems with mitigation measures is a source of inspiring public confidence in these PHPs.

Integration of PV in PHPs is thus crucial in their success and plays an important opportunity in the ultimate cost saving through early recognition and management of HPT-related problems. It is therefore important for PHPs to invest in PV. This document demonstrates the importance of collaboration and communication between the National Pharmacovigilance center and the PHPs to ensure the integration of PV as an essential component of PHPs. The document shall also promote the understanding of PV, education and clinical training strategies, and effective communication to the public and other health care providers.

1. INTRODUCTION

The 21st century started with the devastation caused by the HIV/AIDS pandemic which helped draw attention to the lack of access to medicines in resource constrained areas and particularly sub-Saharan Africa. In response to this, new funding sources, such as the President's Emergency Plan for AIDS Relief, the President's Malaria Initiative, and the Global Fund to Fight AIDS, Tuberculosis and Malaria, made unprecedented sums of money available to procure essential medicines, including new products such as antiretroviral (ARV) medicines for HIV/AIDS, artemisinin-based combination therapies (ACTs) for malaria, and second-line medicines for multidrug-resistant tuberculosis.

The ongoing COVID-19 pandemic as declared on March 11, 2020, has introduced the need for strong infection prevention and control as a major intervention for controlling the spread of COVID-19. In response to this pandemic, there has been the introduction of new COVID-19 vaccines and there are several medicines that are under the development process with undergoing clinical trials.

With increased access to existing and new essential medicines, vaccines, other Health Products and technologies comes a greater need to monitor and promote the safety and effectiveness of these HPTs. Few developing countries, however, have the structures, systems, or resources in place to support medicine and vaccine safety activities. Countries often lack unbiased, evidence-based information to help guide treatment decisions and promote rational use—that is, safe, effective, and cost-effective—use of medicines.

In addition, sustained budgetary support for pharmacovigilance and medicine safety activities is generally lacking. Many studies have reported the huge impact that poor product quality, adverse drug reactions (ADRs), and medication errors have on health care in general and on patients' health in particular, but because most cases go undetected, estimating the actual scale of this burden is almost impossible.

Authors of a meta-analysis estimated that ADRs alone excluding medication errors killed over 100,000 people in 1994 and were the fourth to the sixth leading cause of death in the United States (Lazarou et al. 1998). A similar study estimated that over 70 per cent of ADRs that resulted in hospitalization in the United Kingdom could have been avoided (Pirmohamed et al. 2007). Adverse drug events (ADEs) also are costly in terms of patients' loss of trust in the health care system. The costs in lives and money are great in high-income countries, but the situation in low- and middle-income countries is likely to be much worse because of the poorer state of health system infrastructure, unreliable supply and quality of medicines, and lack of adequately trained health care staff.

Many developing countries are now recognizing the need to set up systems to monitor the safety of newly introduced medicines, vaccines, and other health products and technologies including antiretrovirals, antimalarials, antituberculosis and vaccines but they often lack the resources, including in-country expertise, to design or build or implement strong pharmacovigilance systems.

Pharmacovigilance is defined by WHO as "the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems". The term 'pharmacovigilance' is often used in a generic sense, to refer to the monitoring of adverse events for other health products and technologies. In other circumstances, more specific terms can be applied, e.g. for health technologies (techno vigilance); and for blood and blood products (haemovigilance), Vaccines (Vaccinovigilance) and toxic substances (Toxivigilance).

Strengthening pharmacovigilance systems to promote patient safety requires a multi-pronged approach and success is informed by strong leadership by the National Regulatory Authorities and coordination of all key institutions including the public health programs players and other stakeholders.

2. Legal framework

The regulation for the conduct of pharmacovigilance activities is governed according to the Pharmacy and Poisons Act, Cap 244 Laws of Kenya Subsidiary Legislation, Pharmacy and Poisons (Registration of Drugs) Rules 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 medical products and health technologies".

3. Purpose

The purpose of this document is to highlight the role of the Pharmacy and Poisons Board and Public Health Programs in strengthening an integrated vigilance of health products and technologies to safeguard public health; and minimize the use of unsafe, ineffective, substandard and falsified medical products and promote safety monitoring.

The document aims to inform and guide the actions of Public Health Programs (PHP) in their efforts to enhance reporting of adverse events (AE), adverse drug reactions (ADRs), Adverse Events following immunization (AEFIs), medication errors, blood transfusion reactions and the overall safety of the Health Products and Technologies which, are provided to the public under these programs. The key objectives of intergating Pharmacovigilance in PHPs are to;

i. To improve public health and safety in regards to the use of HPTs in PHPs
ii. To support the detection of HPT related problems and provide associated risk communication in a timely and effective manner
iii. To promote the rational use of HPTs through selection of safe and effective products.

4. Scope

This guideline aims to provide a framework for collaboration between Pharmacy and Poisons Board (PPB) and all the Public Health Programs (PHPs) in the country. The guideline applies to all public health programs in the country. They include but are not limited to; Division of National Malaria

Program (DNMP), National Tuberculosis, Leprosy, and Lung Disease Program (NLTP), National AIDS & STI Control Program (NASCOP), National Vaccines & Immunization Program (NVIP), Division of Reproductive and maternal Health (DRMH), Division of Neonatal, Child and Adolescent Health Unit, Kenya Tissue and Transplant Authority (KT&TA), Neglected Tropical Diseases Unit (NTD) and Division of Non-Communicable Diseases.

5. Pharmacovigilance system in the global context

The Global Program for International Drug Monitoring is coordinated by the WHO Collaborating Centre for International Drug Monitoring in Uppsala, Sweden – the Uppsala Monitoring Center (UMC). The UMC maintains a repository of suspected Adverse Drug Reactions (ADRs) and Adverse Events Following Immunization (AEFI) reports which, are reported by national PV centers. All National PV centers collaborate with the WHO Program for International Drug Monitoring, to collect reports of these Individual Case Safety Reports (ICSR) and after review, send them to the UMC for entry into the WHO database. This is the largest database of ADR reports in the world (over 17 million ICSRs) and is a prime resource for generating signals of previously unrecognized ADRs/AEFIs and for the study of questions on the safety of medicines.

To guide countries on the safety of medicines, the WHO has outlined the responsibilities of public health programs in pharmacovigilance. The guideline was triggered by the rapid expansion of public health programs, in response to the rapid growth of international funding mechanisms that were putting unprecedented amounts of new essential medicines in lower and middle-income countries, with limited information on the safety profiles of such medicines in the LMIC populations. This called for continuous and nationally coordinated monitoring of their safety.

5.1. Functions of a National Regulatory Authority for Health Products and Technologies

The WHO outlines the overall objective of the National Regulatory Authority (NRA) for health products as: "*to ensure that all medicines (drugs, vaccines,*

blood products, and other biologicals) and medical devices are of assured quality, safety, and efficacy and are accompanied by appropriate information to promote their rational use".

To achieve the above objective, Governments should assign the NRA effective legal powers, independence in decision-making, and autonomy to recruit and dismiss staff. Also, the NRA must exercise all critical control functions. These are:

- Licensing (of products, manufacturers, and distributors).
- Laboratory testing and lot release (where required).
- Inspections of manufacturing sites and distribution facilities.
- Control of clinical trials.
- Control of advertising and promotion.
- Post-marketing surveillance of quality, safety and rational use.

The function of vigilance falls within the post-marketing surveillance for safety and quality. It entails the detection, assessment, understanding, prevention, and communication of adverse events, following the use of a health product or technology. The collection of AE data is through spontaneous reporting, as well as targeted reporting, e.g. through sentinel surveillance or cohort event monitoring

5.2. Pharmacovigilance system in the Kenyan Context

The Pharmacy and Poisons Board ("the Board") is the National Regulatory Authority (NRA) in Kenya and was established under an Act of Parliament, the Pharmacy and Poisons Act, Cap 244, Laws of Kenya. The National Pharmacovigilance Center (NPC) was established in 2004.

The Board set up a Pharmacovigilance (PV) reporting system which was officially launched in 2009 followed by the implementation of the national PV guidelines, job aids and training package.

In May 2010, Kenya became the 98th full member of the World Health Organization (WHO) Program for International Drug Monitoring. Currently, over 16,000 individual case safety reports have been uploaded to the WHO global database (VigiBase).

In April 2013, Kenya launched the pharmacovigilance electronic reporting system (PvERS), the 1st VigiFlow-compatible e-reporting system in Africa (www.pv.pharmacyboardkenya.org) with support from USAID funded Health Commodities and Services Management Program implemented by Management Sciences for Health.

In May 2014, the Kenya Pharmacy and Poisons Board was nominated by AUDA NEPAD as one of the Regional Centers of Regulatory Excellence (RCORE) in Pharmacovigilance in Africa.

In 2021, with seed funding from the WHO, PPB upgraded the PVERS to include the AEFI reporting form and other reporting forms for medication errors, transfusion reactions and medical devices incidents/events. Later, the USAID Medicines Technologies and Pharmaceutical Services (MTaPS) program upgraded the PVERS to a mobile version, the mPvERS with applications on Android and iOS platforms and an accompanying USSD Code *271# for enhancing reporting by the members of the public. The mPVERS and USSD code were launched in April 2022.

Over the years, the Kenya PPB has engaged public health programs and other stakeholders in the pharmacovigilance agenda at the national and county levels. The National Pharmacovigilance Centre shall work in collaboration with the Public Health Programs (PHPs) to develop and promote Pharmacovigilance in the PHPs and sensitize healthcare providers to report adverse reactions and medication errors including irrational use of medicines. It shall jointly decide with the PHP continuously, whether all or only a few priority medicines shall be monitored, the duration of monitoring and the time frames for reporting and action.

A key challenge faced by the PPB is the limited understanding of the role of safety monitoring among public health programs and the public. In Kenya, hundreds of healthcare providers have been trained on pharmacovigilance – either directly by the PPB or through training programs supported by WHO and other development partners. However, various programmatic changes within public health programs, including attrition of personnel within these national programs and health facilities, have created the constant need for more training and the re-orientation. Another challenge is that the current PVERS is not linked to the Kenya Health Information System (KHIS) and other data reporting platforms used by the various Public Health Programs. This creates a barrier to health products and technologies safety information sharing between these programs and the PPB.

5.3. Pharmacovigilance Requirements for Public health programs

PHPs are generally vertical programs with intense activities that aim toward specific health problems by administering HPTs either for prophylaxis, treatment and eradication. Interventions aimed at reducing morbidity and mortality include mobilization of local and international resources to support the implementation of the programs, including mass distribution of HPTs.

Traditionally the scope of monitoring in PHPs has been more focussed on: the incidence and prevalence of diseases , the morbidity and mortality rates as a result of the disease, number of patients treated and number of HPT units delivered. There is however need to broaden this scope by including benefit risk assessment and effectiveness of these HPTs to be able to detect, evaluate and prevent any adverse events. PHPs should therefore work collaboratively with the National Pharmacovihalnce Centre to ensure rational and safe use of HPTs by healthcare providers and professionals. They should also assess and communicate the risks and benefits, effective use of HPTs and educate and inform patients on any updates.

It is important that the PHPs designate focal persons for Pharmacovigilance and Post-market surveillance to support the coordination and integration of

pharmacovigilance activities between PHPs , National Pharmacovigilance Centre and their program focal persons within the counties.

5.4. Overview of the Role of national public health programs

The Kenya Public Health Programmes are established to enable the national MOH to coordinate the delivery of public health interventions to the entire population. Currently, there are at least 9 public health programs as shown in the table 1:

Table 1: Key Public Health Programmes in Kenya

#	Program	Name of unit
1.	Malaria	Division of National Malaria Program (DNMP)
2.	Tuberculosis	National Tuberculosis, Leprosy and Lung Disease Program (NLTP)
3.	HIV	National AIDS & STI Control Program (NASCOP)
4.	Immunization	National Vaccines & Immunization Program (NVIP)
5.	Reproductive and Maternal Health	Division of Reproductive and maternal Health (DRMH)
6.	Neonatal, Child & Adolescent Health	Division of Neonatal, Child and Adolescent Health Unit (NCAH)
7.	Blood Transfusion	Kenya Tissue and Transplant Authority (KT&TA)
8.	Neglected Tropical diseases	Neglected Tropical Diseases Unit (NTD)
9.	Non-communicable diseases	Division of Non Communicable Diseases (NCD)

The overall objective of this document is to outline the roles of the national Public Health Programs in pharmacovigilance, the areas of collaboration and

strategies to support the PPB to fulfil its role in safety monitoring and surveillance.

Below is an overview of some roles of the PHPs in Pharmacovigilance:

i. Providing leadership in vigilance of Health Products and Technologies within their specific programs.
ii. Collaborating with the PPB in processing vigilance information for health products and technologies related to the specific PHP, and guiding programs-based decision-making for overall vigilance improvement.
iii. Facilitating planning and coordination of national and sub-national vigilance based on agreed coordination structures to ensure optimal and efficient programs responses to ADRs and AEFIs.
iv. Facilitation of partnerships with WHO, PPB, and Expert safety committees in identifying priority goals and actions for quality program outputs relating to specific HPTs.
v. Contributing to Learning and the PHP's Policy development agenda through facilitating documentation of lessons learned, best practices and supporting surveys and research studies to answer Pharmacovigilance questions arising from implementation and use of specific health products and technologies at the service delivery and consumer level.
vi. Ensuring collection, synthesis, and production of quality Pharmacovigilance reports and their transmission to PPB to facilitate a joint review, discussion, and informed decision-making on the improvement of the programs and utility of the given products.
vii. To contribute to and support the strengthening of the Pharmacovigilance electronic reporting system (PVERS) which, consolidates PV information regarding Health Products and Technologies from various PHPs and the field, thus enabling information capture in a central repository or within the defined Country's reporting and feedback system, for synthesis and sharing

to contribute to the global community of practice and in-country programs improvement.

6. Roles and responsibilities of specific public health Programs in Pharmacovigilance

ROLES	DNMP	NLTP	NASCOP	NVIP	DRMH	NCAH	BT	NTD	NCD
Provide public information during the launch of new health products and technologies (HPTs) including new vaccines;	√	√	√	√	√	√	√	√	√
Ensure training of health facility staff in the use HPTs and monitoring for any adverse events that may arise;	√	√	√	√	√	√	√	√	√
Conduct passive and active surveillance of HPTs in collaboration with the Board;	√	√	√	√	√	√	√	√	√
When necessary, be called upon by the Board to determine the risk-benefit assessment of HPTs, in order to update treatment guidelines and initiate new training and communications to health providers and the general public;	√	√	√	√	√	√	√	√	√
Provide technical support to the investigation teams on quality and safety issues at the County and Sub-County levels;	√	√	√	√	√	√	√	√	√
Conduct post-marketing quality surveys of HPTs in collaboration with the Board;	√	√	√	√	√	√	√	√	√

ROLES	DNMP	NLTP	NASCOP	NVIP	DRMH	NCAH	BT	NTD	NCD
Participate in activities of the National Pharmacovigilance and Post-marketing surveillance Technical Working Group;	√	√	√	√	√	√	√	√	√
Make programmatic decisions as concerns matters related to quality, safety, and efficacy of HPTs;	√	√	√	√	√	√	√	√	√
Conduct education, training, and advocacy to the relevant stakeholders;	√	√	√	√	√	√	√	√	√
Plan and budget for pharmacovigilance activities; and mobilize resources for PV and PMS activities.	√	√	√	√	√	√	√	√	√
Promote product safety vigilance among PHP stakeholders,	√	√	√	√	√	√	√	√	√
Designate a Vigilance focal point for the programs	√	√	√	√	√	√	√	√	√
Liaise with PV Center and decide jointly on the vigilance goals and priority actions	√	√	√	√	√	√	√	√	√
Access data from the PV Center	√	√	√	√	√	√	√	√	√
Provide timely and comprehensive product safety reports to the PPB and avail a monthly update, including 'zero reporting' to the Board.	√	√	√	√	√	√	√	√	√
To collaborate with the Board to develop and operationalize a reporting				√					

ROLES	DNMP	NLTP	NASCOP	NVIP	DRMH	NCAH	BT	NTD	NCD
and feedback pathway or framework for constructive and efficient flow of critical reports from service providers and facilities.									
To participate in joint review of Country PV data pertaining to vaccine safety and provide the NVSAC and the Board with monthly reports in agreed format to facilitate National review of PV programs performance.				√					
Collaborate with the Board to review the electronic reporting system (s) and any other applicable data system for collection, collation, analysis, and dissemination of AEFI reports at all levels.				√					
To jointly work with the Board and other partners to provide appropriate and coordinated responses in 'crisis management' to manage the media, political elite and opinion leaders in controversial situations related to vaccines.				√					
To facilitate program's learning (PL) by collaborating with the Board in scientific inquiry relating to challenges surrounding pharmacovigilance at sub-national level to inform the Board and NVIP PV program's response.				√					

ROLES	DNMP	NLTP	NASCOP	NVIP	DRMH	NCAH	BT	NTD	NCD
To liaise with WHO and partners to provide 'communication trainings' to the Board's focal points relating to immunization AEFIs, thus capacity building the Board as a ready partner in 'crisis management' during vaccine introductions and implementation.				√					

7. Strategies to improve vigilance and market surveillance of health products and technologies in public health programs

To enhance vigilance and market surveillance for Health Products and Technologies within Public Health Programs, the following strategies shall be jointly explored by the Board and the PHPs.

Strategy Area	Actions
Capacity Building/Training	- In collaboration with the Board and other development partners, the PHPs to conduct trainings to health workers and other stakeholders on the importance of safety monitoring of health products and technologies including reporting all suspected events /incidences/medication errors/therapeutic ineffectiveness and quality defects. - Jointly conduct education, training and advocacy to the relevant stakeholders; - Organize training on causality assessment, signal detection and communication; in collaboration with WHO, the Board & expert committee members - Intensify training on program-specific AEs – as needed, and informed by reporting data and trends - Lobby with the relevant stakeholders for employment/deployment of staff to spearhead vigilance functions of the PHPs at the national and sub national levels

Strategy Area	**Actions**
Pharmacovigilance Reporting systems	- Advocate for use of the national pharmacovigilance and post marketing reporting systems by PHPs in order to leverage on resources & avoid parallel reporting systems - Enhance awareness at the service delivery level on existence and use of electronic reporting system by service providers and consumers: - Pharmacovigilance Electronic Reporting System (PvERS) - Mobile Pharmacovigilance Electronic Reporting System (mPvERS) - USSD code (*271#) for patients and care givers - Periodic joint review of the system with the Baord to address identified gaps for continuous improvement of the system. - Collaborate with PPB for interlinkage of the Board's PvERS/mPvERS and other National and PHP specific product safety reporting systems e.g., KHIS, Chanjo, TIBU etc. for coordinated data collation, analysis and utilization
Enhanced Reporting and Investigation of reported ICSRs	- Continued advocating for, and facilitating improved reporting by healthcare providers. - Facilitate 'Qualitative studies' to delve deeper into the 'root causes' of Adverse events non-reporting in order to inform evidence-based PV programs response. - Facilitate establishment and institutionalization of a reporting & feedback pathway for reports, results for the national and sub national level to enhance 'revision and improvement of the PHP PV performance and PPB PV programs overall. - Implement targeted advocacy to stakeholders specific to the PHP. - Collaborations on rapid surveys to answer questions on perceived programmatic challenges affecting non-reporting to inform PHPs in PV response and improve the PV programs. - Support PHP and PPB collaboration in operationalizing this reporting and feedback pathway through incorporating it in

Strategy Area	**Actions**
	their 'National and County, sub-County review forums and meetings'.
Joint working modalities (Linkage with other PHPs)	- Strengthen the operations of the PV/PMS technical working group; in order to facilitate regular interaction between the PPB and PHPs on Vigilance; enhance joint learning and optimize benefits to PHPs.
Documents and Tools	- Jointly Develop/Review vigilance tools and guidelines - Jointly develop/review PHPs manuals and guidelines to ensure incorporation of Vigilance activities. Develop key performance indicators for implementation, monitoring and evaluating the effectiveness of Pharmacovigilance within the programs.
Communication	- Work jointly to enhance communication on Health Products and Technologies safety, including timely and appropriate feedback to those who report ICSRs. - Strengthen the dissemination of summaries of ICSRs via e-shot email alerts, newsletters and other mechanisms as shall be prescribed from time to time. - The PHP PV focal persons provided with access rights under PPB defined policies to ensure them make timely critical programmatic decisions and actions.

8. Joint integrated activities for PV and PMS

Safety monitoring of Health Products and Technologies is one of the key activities in Pharmacovigilance and Post Marketing Surveillance. This can either be done through active surveillance or targeted spontaneous reporting, investigation and review of serious reported cases (Causality assessment), conduct of post market surveillance for PHP health products

and technologies, training of healthcare providers on Pharmacovigilance incorporating modules specific to PHPs and dissemination of information. To ensure efficient use of the limited resources, it is therefore necessary that PPB jointly works with respective Public Health Programs to implement these activities.

9. Use of PV and PMS data for decision-making by PHPs.

Pharmacovigilance data refers to information collected as a result of intentional detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem, with the aim of enhancing patient care and patient safety in relation to the use of medicines; and supporting public health programs by providing reliable, balanced information for the effective assessment of the risk-benefit profile of medicines.

The key interest in having Pharmacovigilance and Post Marketing Surveillance incorporated into the Public Health Programs is due to diseases-tropical, comorbid conditions, insufficient follow-up, not well diagnosed, population-low living standards, cultural behavior, off-label use, drugs-mass distribution, suspected poor quality or falsified new molecules, donated drugs, poor storage of drugs and health care system-no PV system, poor medical services, financial shortages.

Pharmacovigilance and Post marketing Surveillance shall therefore detect and evaluate the data received and provide PHP with evidence-based recommendation to inform policy changes if required. It shall also prevent adverse events, promote rational use of drugs in mass treatment programs, evaluate the impact of the programs and improve the acceptability of the Programme. Data sharing is key for both the Board and public health programs. The number of reports of particular events can be used to calculate incidence if the denominator is known. Programs should be available and shall sort the data appropriately, e.g. different types of the event by System Organ Class, or to enable analyses of possible risk factors

such as age. This shall help in preventing harm to the greater public if handled at the appropriate time.

10. Schedules of meetings between PPB and PHPs

PPB and PHPs shall meet on a quarterly basis. Ad Hoc meetings shall also be planned as need arises. In addition, to physical meetings, the team may also conduct its meetings virtually as and when needed. The meetings shall either be between PPB with all PHPs, PPB with some PHPs, or PPB with a specific PHP depending on the relevance of the agenda to be tackled.

The agenda of meetings shall be prepared and shared with members at least seven days before the meeting day so as to enable adequate preparation of the members.

11. Communication of serious events between PPB and PHP

Risk communication is a critical aspect of pharmacovigilance that must be considered by organizations during the implementation of PV activities. The main challenges that hinder effective risk communication are its dependence on the perception of stakeholders, underpinned by their opinions, experiences, and emotional responses to risk. This, therefore, requires a strategic level that involves collaborative problem-solving providing an understanding of the strengths and limitations of risk analysis along with tools for internal and external communication to ensure consistent messaging. Ultimately, integrating expert communication with computational methods creates a strong foundation and increases the success of risk communication.

Risk communication aims to provide timely, meaningful, relevant and accurate information, in clear and understandable terms targeted to a specific audience for minimizing the risk burden. The Board in collaboration with the relevant stakeholder shall communicate the risk related to the quality, safety and efficacy of the medical products and health technologies guided by the risk communication procedure for medicine safety.

12. Communication channels

The Board in collaboration with the relevant stakeholder shall use relevant communication tools and channels when issuing safety/risk communication. They shall include but not limited to the following:

1. Direct healthcare professional communication (DHCP).
2. Communication materials targeted at healthcare workers.
3. IEC materials to patients and the general public e.g., brochures, flyers, public alerts.
4. Press communication e.g., press releases, press briefing.
5. Website.
6. Social media and other online communications.
7. Inter-NMRA communication.
8. Responding to inquiries from the public.

Other means such as publications, and scientific and professional journals.

12.1. Monitoring the implementation of Pharmacovigilance and Postmarket Surveillance in PHPs

A set of Pharmacovigilance assessment indicators dedicated to PHPs have been developed to help the PHP managers and the PV/PMS focal persons to plan, monitor and evaluate the effectiveness of PV within their programs. It is important that these activities are planned in close collaboration with the national PV Centre at PPB to avoid duplication of efforts and leverage on the use of the available limited resources.

The indicators are domesticated from the East African Harmonized indicators on Pharmacovigilance assesement that are adopted from the WHO pharmacovigialnce Indicators and the IPAT from MSH. The indicators are listed below;

13. References

1. The safety of medicines in public health programmes: Pharmacovigilance an essential tool (WHO, 2013)
2. AIDE-MEMOIRE: Strengthening National Regulatory Authorities (WHO, 2003)
3. PV/PMS Rules & Regulations 2022
4. desai S. Risk Communication in Pharmacovigilance: Lookouts, Challenges and Strategies . jpadr [Internet]. 2022Sep.1 [cited 2023Mar.21];3(3):1-. Available from: https://www.jpadr.com/index.php/jpadr/article/view/101
5. Guidelines on safety and vigilance of health products and technologies in Kenya, revision 1, 2023.

14. List of contributors

Dr. Fred Siyoi	Chief Executive Officer PPB
Dr. Ahmed Mohammed	Director, HPT, PPB
Dr. Kariuki Gachoki	Deputy Director, PDS, PPB
Dr. Khaemba Christabel	Head, PV,PPB
Dr. Karim Wanga	Head PMS,PPB
Dr. Mandale Martha	Regulatory officer PV ,PPB
Dr. Nambwa Pamela	Regulatory officer PV, PPB
Mr. Muthuri George	Regulatory officer QMS, PPB
Dr. Kusu Ndinda	Country Project Director, MTaPS
Dr. Joseph Mukoko	MtaPS
Dr. Elias Onyango	MTaPS

15. Annexes

Annex 1: PUBLIC HEALTH PROGRAMS

Indicators: C- Core | **S**- Structural | **P**- Process | **O**- Outcome

	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting
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.*		Yes	Strategic and/or Annual operational plans	PHP PV/PMS focal person	Annual
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.*		Yes	PHP Budget	PHP PV/PMS focal person	Annual
					In the last fiscal year, how many funds were allocated by the MOH and donors for pharmaco					

	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting
					vigilance activities? *Please enter the amount in the Answer box and specify the currency in the Notes column.*					
P2.3	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		Yes	Presence of bulletins, Newsletters, Website	PHP PV/PMS focal person	Annual report
					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					

	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting
					safety and PV information?					
					Is there another mechanism for dissemination of PV information? *Please describe the mechanism*					
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.*		TBD	Training reports	PHP PV/PMS focal person	Annual report
					How many training events/sessions were conducted in the previous 12 months? *Request documentation to verify.*					

	Core or Supplementary	**Indicators Type**	**Indicator**	**Frequency of Collection**	**Assessment Question**	**Baseline**	**Target**	**Data Source**	**Responsibility**	**Reporting**
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.*		TBD	Treatment guidelines or protocols	PHP PV/PMS focal person	Annual report
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.*		Yes	Standard Treatment Guidelines or Policies	PHP PV/PMS focal person	Annual report
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?		Yes			Annual report
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 pharmacovi	Annual	What is the number of AE reports received by the PHP in the previous 12 months?			ADR/AE Reports	PV/PMS focal person	Quarterly Report

	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting
			gilance center 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?					
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)?			Study Protocol	PV/PMS focal person	Annual report
					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					
P4.3	S	O	Percentage of patients in public	Annual	What is the total number			AE Reports	PV/PMS focal	Annual report

	Core or Supplementary	Indicators Type	Indicator	Frequency of Collection	Assessment Question	Baseline	Target	Data Source	Responsibility	Reporting
			health programs for whom drug-related, serious unexpected adverse events were reported in the previous 12 months		of patients receiving medicines under the PHP? *Request documentation to verify.* What is the total number of patients receiving medicines in the PHP who experienced drug-related, serious, unexpected adverse events? Request documentation to verify.				person	
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	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?		TBD	Supervision reports	PV/PMS focal person	Annual Report

	Core or Supplementary	**Indicators Type**	**Indicator**	**Frequency of Collection**	**Assessment Question**	**Baseline**	**Target**	**Data Source**	**Responsibility**	**Reporting**
			and the public		*Please enter your answer in days.*					
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	PV/PMS focal person	Quarterly Report
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?		Yes	Newletter, bulletin or publication	PV/PMS focal person	Quarterly Report
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

	Core or Supplementary	**Indicators Type**	**Indicator**	**Frequency of Collection**	**Assessment Question**	**Baseline**	**Target**	**Data Source**	**Responsibility**	**Reporting**
					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 (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.*				PV/PMS focal person	Quarterly Report
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			Activity Report	PV/PMS focal person	Quarterly Report

	Core or Supplementary	**Indicators Type**	**Indicator**	**Frequency of Collection**	**Assessment Question**	**Baseline**	**Target**	**Data Source**	**Responsibility**	**Reporting**
					previous 12 months? *Request documentation to verify.*					

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