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MINISTRY OF HEALTH

PHARMACY AND POISONS BOARD

IMPLEMENTATION PLAN FOR ACTIVE SURVEILLANCE

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Abbreviations and Acronyms

CEM	Cohort Event Monitoring
ERC	Ethics and Research Committee
HCP	Health Care Provider
HPTs	Health Products and Technologies
MOH	Ministry of Health
PDS	Product Safety Department
PHP	Public Health Program
PPB	Pharmacy and Poison Board
SOP	Standard Operating Procedures
WHO	World Health Organization

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 - Any untoward medical occurrence in a patient or clinical investigation subject administered a Health Products and Technology (HPT) and which does not necessarily have a causal relationship with the treatment.

Causal association - A relationship between one phenomenon or event (A) and another (B) in which A precedes and causes B. In pharmacovigilance, a medicine causing an adverse reaction.

Individual case safety report (ICSR) - A report that contains information describing a suspected adverse drug reaction related to the administration of one or more medicinal products to an individual patient.

Serious adverse event – An adverse event which either leads to death or a life-threatening experience; hospitalization or prolongation of hospitalization; persistent significant disability; congenital anomaly.

Signal - Reported information on a possible causal relationship between an adverse event and a medicine or vaccine, the relationship being unknown or incompletely documented previously or representing a new aspect of a known association. The information may arise from one or multiple sources that are judged to be of sufficient likelihood to justify verification.

Study coordination team - an investigative team for active surveillance led by a team lead qualified by education, training, and experience.

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Preface

The Pharmacy and Poisons Board (PPB) is the authority mandated, by Cap 244 of the Laws of Kenya, to regulate the Practice of Pharmacy and the manufacture and trade of drugs and poisons. The Pharmaceutical Industry has seen rapid growth since the enactment of the Act. Despite the obvious benefits of Health Products and Technologies (HPTs), they are known to have a possibility of causing adverse events, which can be serious or even fatal. The safety and quality of these HPTs must be continuously monitored by key industry players to ensure patient safety.

Active surveillance systematically documents and quantifies the incidence rate of adverse events associated with HPTs. In addition, it generates data to provide better estimates of risk-benefit profiles and help prevent and minimize such risks to patients on treatment. The purpose of this guideline is to provide guidance on the process of conducting active surveillance in Kenya

1.0 INTRODUCTION

1.1 Background

The World Health Organization (WHO) defines Pharmacovigilance as "the science and activities related to the detection, assessment, understanding and prevention of adverse events or any other possible drug-related problems." There are two major approaches for pharmacovigilance: passive and active. Passive pharmacovigilance entails spontaneous (voluntary) reporting while active pharmacovigilance involves the use of active surveillance methods to gather information on adverse events. Active surveillance is the collection of case study information as a continuous pre-organized process. It involves proactive measures to identify adverse events, extending beyond merely encouraging healthcare providers (HCPs) and others to report voluntarily.

Active surveillance systematically documents and quantifies the incidence rate of adverse events associated with Health Products and Technologies (HPTs). In addition, it generates data to provide better estimates of risk benefit profiles and help prevent and minimize such risks to patients on treatment. Active surveillance may be conducted for the purpose of identifying previously unrecognized safety concerns (hypothesis generation) or for investigating potential and identified risks (hypothesis-testing in order to substantiate a causal association). Consequently, this will decrease the negative impact of these events on the health of individuals and public health programs and maintain or increase the confidence of HCPs and the general population on HPTs use.

In Kenya, pharmacovigilance activities have predominantly been passive, with heavy reliance on spontaneous reporting where individual case safety reports (ICSRs) are submitted voluntarily to the Division of Pharmacovigilance, Pharmacy & Poisons Board (PPB). However, a few active surveillance studies have been conducted especially when new HPTs are introduced in the Kenyan market.

The aims of active surveillance include:

i) To facilitate early detection, investigation, and analysis of adverse events to ensure an appropriate and rapid response.

ii) To generate data for characterizing the safety profile of HPTs.

1.2 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".

1.3 Scope

The objective of this guideline is to provide guidance for conducting active surveillance in Kenya. This implementation plan shall apply to all entities, institutions, and individuals conducting active surveillance in Kenya. They include but are not limited to: The Pharmacy and Poisons Board (PPB), Public Health Programs (PHPs), the Ministry of Health (MOH), County Governments, health facilities, research institutions, academia, and non-governmental organizations. The guideline shall guide the conduct of active surveillance for Health Products and Technologies (HPTs) registered in Kenya, including those already on the market and those newly introduced to the market.

2.0 ACTIVE SURVEILLANCE

2.1 Utility of active surveillance

Active surveillance may be undertaken to:

a) Detect safety concerns associated with newly introduced health products and technologies (HPTs), including adverse events not identified during clinical trials.

b) Characterize new or clinically significant adverse events associated with a specific HPT or class of HPTs.

c) Investigate increases in the frequency of reported adverse events associated with an HPT or class of HPTs.

d) Monitor, confirm, or further characterize the known safety profile of HPTs with established safety concerns.

e) Identify risk factors for adverse events in special populations, including children, pregnant women, and other vulnerable groups.

2.2 Approaches of active surveillance

The choice of an active surveillance approach shall be guided by the surveillance objectives, the characteristics and risk profile of the health product and/or technology, the target population, and available resources. Active surveillance shall employ standardized case definitions, predefined data collection methods, quality assurance measures, and appropriate mechanisms for data analysis and follow-up. The evidence generated should complement spontaneous reporting systems to support signal detection, benefit–risk assessment, regulatory decision-making, and risk minimization. Where feasible, national electronic medical record systems, registries (e.g. patient and pregnancy registries), healthcare databases, and disease surveillance systems shall be leveraged to

support active surveillance. Active surveillance activities shall be conducted in collaboration with the Pharmacy and Poisons Board (PPB).

The three main approaches to active surveillance include:

2.2.1 HPT-based active surveillance

This involves the systematic and continuous collection of safety information from individuals exposed to a specific HPT or class of HPTs. This approach is particularly appropriate for newly introduced HPTs, products under additional monitoring, HPTs with identified or potential safety concerns, or products requiring post-authorization safety studies. Data may be collected through structured systems such as patient registries, cohort event monitoring, pregnancy exposure registries, disease registries, or other organized follow-up mechanisms.

2.2.2 Setting-based active surveillance

This is the systematic and continuous collection of safety information within a defined health care setting where patients receive treatment. These settings may include hospitals, health centres, specialist clinics, pharmacies, immunization clinics, or disease-specific treatment programmes.

2.2.3 Event-based active surveillance

This involves the proactive identification, investigation, and follow-up of predefined adverse events of special interest (AESIs) or other clinically significant events that may be associated with one or more HPTs.

2.3 Methods of Active Surveillance

2.3.1 Sentinel Site Surveillance

This method involves the systematic collection of safety data from selected sentinel sites which may include healthcare facilities, laboratories, or other designated reporting sites. These sentinel sites are selected either randomly or intentionally and serve as reporting sources. Personnel at these sites actively identify, collect, and report all adverse events that meet certain predefined criteria. Sentinel site surveillance allows for gathering more complete and

accurate data, the early detection of new or emerging safety concerns, and the monitoring of the frequency and burden of adverse events within defined populations.

2.3.2 Cohort Event Monitoring

Cohort Event Monitoring (CEM) is the prospective, longitudinal follow-up of a defined group of patients (i.e., the cohort) exposed to one or more HPTs for the purpose of identifying and documenting adverse events. Although the implementation of CEM requires more resources than spontaneous reporting, it allows for the early detection of signals and provides data that is more complete and less susceptible to reporting bias. CEM is an intensive active surveillance method particularly useful for the monitoring of HPTs newly introduced into the market.

2.3.3 Registry-Based Active Surveillance

This method involves the systematic monitoring of patient, disease, or HPT registries to identify and evaluate adverse events associated with specific HPTs or patient populations. This approach is particularly useful for monitoring the safety of HPTs in special populations, such as pregnant women, children, older adults, and patients with chronic diseases, through dedicated registries (e.g. pregnancy exposure registries). In pregnancy registries, both maternal and infant outcomes shall be monitored, with follow-up of the child for a predefined period, at least six months or longer where appropriate, to assess the safety of in utero exposure to the health product of interest. This method supports the assessment of long-term safety, treatment outcomes, and risk factors under routine clinical practice.

2.3.4 Case-Control Studies

These are predominantly retrospective epidemiological studies widely used in epidemiology, and which may be applied for active surveillance. A group of patients who have experienced a particular adverse event is compared with another comparable group of patients who have not experienced the adverse

event, thereby allowing for the association between the use of an HPT and an adverse outcome to be investigated. This method is particularly useful for investigating rare adverse events and identifying potential risk factors.

2.3.5 Record Linkage

This involves the systematic collation and monitoring of patient data on adverse events from multiple data sources such as electronic medical record systems, disease registries, laboratory information systems, health insurance claims, and mortality databases.

3.0 GUIDE TO CONDUCTING ACTIVE SURVEILLANCE

3.1 Steps for conducting active surveillance

3.1.1 Formation of an active surveillance coordination team

A surveillance coordination team led by a team lead qualified by education, training, and experience shall be established by the sponsor of the active surveillance.

3.1.2 Notification of the Intention to Conduct Active Surveillance

The study coordination team lead, or their designated representative, shall communicate their intention to conduct active surveillance in writing to the PPB Product Safety Department (PDS), via email at pv@ppb.go.ke.

3.1.3 Development of the Active Surveillance Protocol

A study protocol shall subsequently be developed to guide the conduct of the surveillance. Every aspect of the methodology must be explicitly stated, including the target population, specific study site(s), sample size, a list of adverse events of special interest if applicable, and any other pertinent information that constitutes a comprehensive protocol.

3.1.4 Ethical approval

Approval for the active surveillance protocol shall be obtained from the pertinent Ethics and Research Committees (ERCs) as well as the National Commission for Science, Technology and Innovation (NACOSTI), and documentation of such approval shall be attached to the protocol. If the research is conducted within Counties, approval from the respective County Research Department must also be secured. Ethical approval shall remain valid throughout the duration of the active surveillance.

3.1.5 Registration of the Active Surveillance Protocol

A copy of the approved protocol, including the accompanying ethical approvals and NACOSTI licence, shall be submitted to the PPB via email at pv@ppb.go.ke.

3.1.6 Active Surveillance implementation

The implementation of active surveillance shall be conducted in accordance with the approved protocol, applicable ethical requirements, and relevant regulatory requirements. It shall include systematic data collection, management, analysis, and reporting to ensure the generation of reliable safety data. Any protocol deviations or non-compliance shall be documented, investigated, and managed appropriately. Significant or persistent non-compliance that compromises participant safety, data integrity, or the scientific validity of the active surveillance may result in its suspension or termination by the Board. In addition, the MAHs shall conduct the post authorization studies as per the requirements prescribed in the Guidelines on the safety and vigilance of health products and technologies under the post-authorization studies section.

3.1.7 Submission of Reports

The individual case safety reports (ICSRs) shall be generated for all adverse events generated during the conduct of the active surveillance and shall be submitted to the Board through the Pharmacovigilance electronic reporting system (PvERS) at www.pv.pharmacyboardkenya.org or mPvERS mobile application for both Android (Play Store) and iOS (App Store).

The timelines for submission of the ICSRs are as follows:

i. All serious adverse events – The Board shall be notified immediately via email at pv@ppb.go.ke, and a report shall be submitted within 48 hours.
ii. Non-serious adverse events shall be reported within 15 calendar days.

All validated serious adverse events identified during active surveillance shall be investigated by the National and/or County/Sub-County investigation teams using standardized tools within 48 hours of receipt of the ICSR, but no later than 7 days. The reports shall be submitted to the Board within 5 days of the initiation of the investigation. The implementing entity shall also conduct an assessment, including causality assessment of these cases and submit its findings to the Board. The Board shall refer the case(s) to the relevant Expert Committee(s) for

causality assessment and recommendations to support regulatory decision-making.

In addition, quarterly summary reports shall be submitted to the Board, throughout the duration of the active surveillance via email at pv@ppb.go.ke. Upon completion of the surveillance, the study coordination team lead on behalf of the implementing entity shall submit a comprehensive final report detailing the methodology, safety findings, analyses, conclusions, and recommendations. Both electronic and hard copies of the final report shall be submitted to the Pharmacovigilance division of the PPB.

3.1.8 Dissemination of findings

The dissemination of active surveillance findings shall be guided by the entity implementing the surveillance and applicable regulatory requirements.

a) For PPB studies, the active surveillance findings shall be disseminated by the PPB in accordance with the internal & external communications procedures.
b) For active surveillance jointly conducted with the PPB, dissemination will be done collaboratively by the participating entities.
c) For studies conducted by other stakeholders in pharmacovigilance, the study coordinator or the principal investigator shall notify the Board of the final results and the intention to publish 30 calendar days before dissemination of the findings.

4.0 MONITORING AND EVALUATION OF THE SURVEILLANCE ACTIVITY

The Board shall monitor all the active surveillance studies conducted in the country to ensure compliance with the approved protocol, applicable regulatory and ethical requirements. The frequency and extent of monitoring shall be determined based on the nature, risk, complexity, and duration of the active surveillance activity and may be conducted on a monthly, quarterly, or other risk-based schedule as determined by the Board.

Some of the approaches utilized by the PV Division to conduct monitoring and evaluation activities includes but are not limited to;

Monitoring and Evaluation Approach	**Objectives**	**Performance Indicators Accessed**
Routine data review	Monitoring of the implementation and performance of the study	Quarterly Summary Reports submitted, Adverse event line list harmonization
Supportive supervision and site visits	Assessment of compliance with study protocols and regulatory requirements	Adherence to SOPs, staff competency, availability of reporting tools, adverse events detected, adverse event submitted to PPB, reporting timeliness, data completeness, investigation/follow-up rate as well as completion
Data quality audits (DQA)	Verify accuracy, completeness, and consistency of data	Missing information, source document verification
Review meetings	Discuss performance, challenges, and corrective actions	Monthly or quarterly pharmacovigilance review meetings. It can be physical or virtual.
Case verification and causality assessment reviews	Ensure quality of adverse event assessment	Percentage of cases assessed within target timelines, consistency of causality assessments with NRA assessment outputs.

5.0 REVISION HISTORY

Revision no.	Date	Section(s) revised	Description of change
1	18/12/2025	Glossary of terms	Addition of the section on glossary of terms
		3.1.7 Submission of reports	Included the requirements of submission of reports including timelines
		4.0 Monitoring and evaluation	Included details on M & E approaches

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