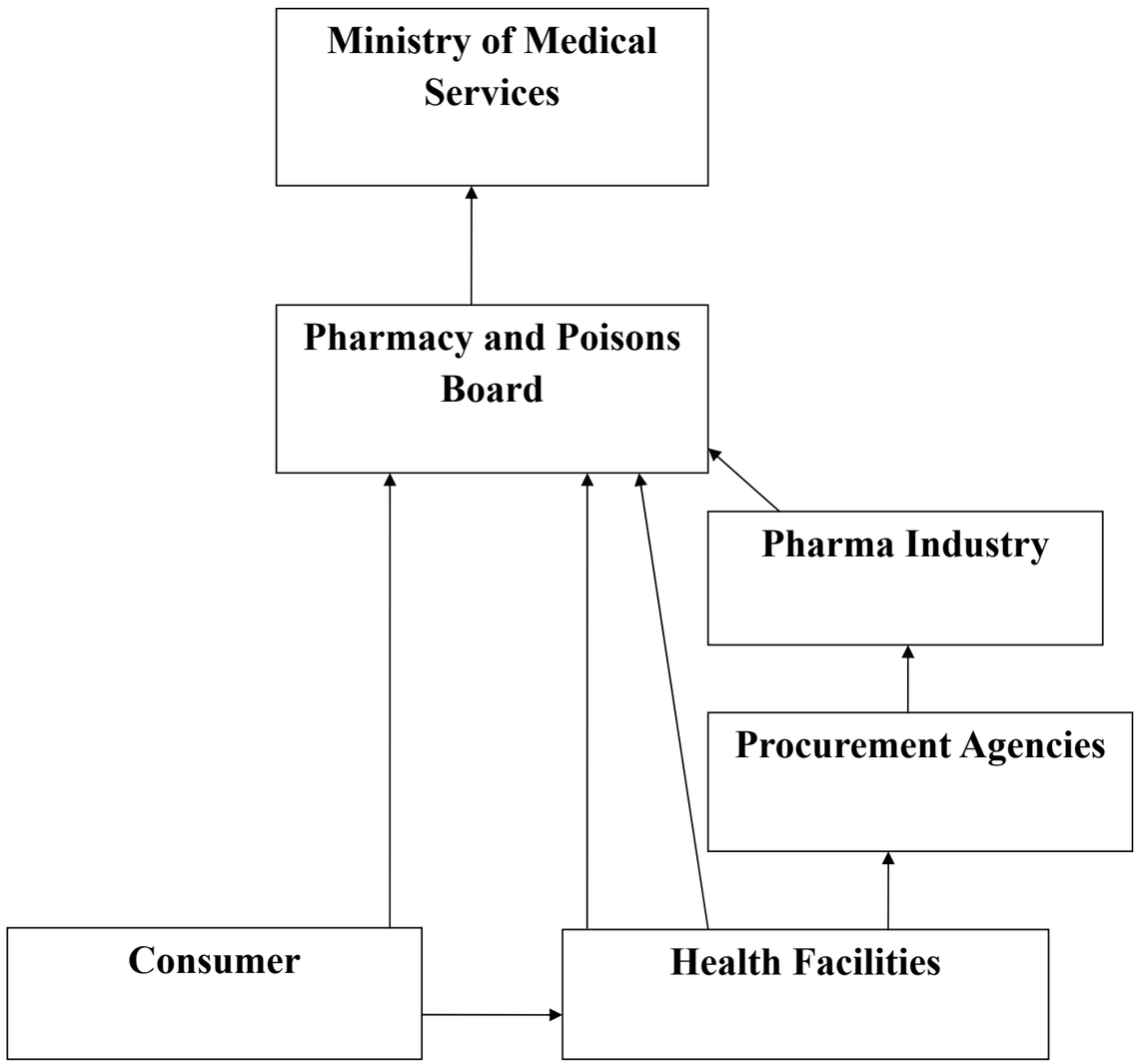

Ministry of Medical Services
Pharmacy and Poisons Board

STRATEGY FOR POST-MARKET SURVEILLANCE (PMS) OF MEDICINES IN KENYA

June 2010

TABLE OF CONTENTS

Appendix iv

Laboratory request form

Appendix iii

Poor quality medicine reporting form (to insert form)

Abbreviations and Acronyms

AIDS	Acquired immunodeficiency Syndrome
DLTLD	Division of Leprosy, TB, and Lung Disease
DOMC	Department of Malaria Control Program
KEMSA	Kenya Medical Supplies Agency
KPA	Kenya Pharmaceutical Association
MOMs	Ministry of Medical services
MOPH&S	Ministry of Public Health and Sanitation
MQM	Medicines Quality Monitoring
NASCOP	National AIDS/STI Control Program
NGO	Non-Governmental Organization
NQCL	National Quality Control Laboratory
PMS	Post Market Surveillance
PPB	Pharmacy and Poison Board
PQM	Promoting the Quality of Medicines
PSK	Pharmaceutical Society of Kenya
USAID	United States Agency for International Development
USP	United States Pharmacopeia
WHO	World Health Organization
MEDS	Mission for Essential Drugs and Supplies
NHSSP II	Second National Health Sector Strategic plan

List of Contributors

1. Dr. K. C. Koskei	Chief Pharmacist, Moms/Registrar, PPB
2. Dr. F. M. Siyoi	Deputy Registrar, PPB
3. Dr. Ronald Inyangala	Head, CPD Program
4. Dr. Jayesh Pandit	Head, Pharmacovigilance
5. Dr. H. Chepkwony	Director, NQCL
6. Dr. Nelly Rangara	Deputy Chief Pharmacist MOMS
7. Dr. Stephen Kimatu	Head, Medicines Information
8. Dr. Andrew Chemwolo	Head, Quality Assurance
9. Dr. Edward Abwao	Department of Pharmacovigilance
10.Ms Anastacia Ngumbi	National Quality Control laboratory
11.Dr. Regina Mbindyo	World Health Organization
12.Mr. Patrick Kibiego	Department of Drug registration
13.Mr. George Muthuri	Department of Pharmacovigilance

List of Reviewers

1. Dr. Andrew Nyandigisi	DOMC
2. Dr, Dorine Kagai	NASCOP
3. Dr. Chris Masila	DLTLD
4. Dr. Wilfred Ochieng	Head, Pharmaceutical Inspectorate
5. Dr. Anthony Torotoich	Department of Drug Registration
6. Dr. Mikal Ayiro	Department of Trade Affairs

Appendix ii

SAMPLING GUIDELINE

FORMULATION	PACK SIZE	MINIMUM NO. OF SAMPLES RE-QUIRED
Tablets/ capsules	All	100 Tablets/Capsules
Suspen-sion/Syrups	≤ 50mL	20 Bottles
	10 – 100mL	
	> 10mL	
	≥100mL	
Injectables	≤10mL	100 Vials/Ampoules
	10 – 100mL	50Vials/Ampoules/ Bottles
	≥100mL	10 Bottles
Creams/Ointments	≤ 5g	50 Tubes
	5 – 50g	20Tubes/Jar
	≥ 50g	5Tubes/Jars
Eye/Ear Drops	< 10Ml	100 Bottles
	≥	50 Bottles
Inhalers	All	10 Packs
Raw material	All	5g

(Sample requirements for Pre-Registration samples)

Samples for other purpose will be decided depending on the test(s) required.

NB: This sample collection form should always be kept with the sample collected. Proper sampling procedures should be followed.
Brief physical/visual description of sample:

.....

.....

.....

.....

.....

Signature of person(s) or representative of the establishment where sample(s) was taken (optional)
1. .....
2. .....

1.0 Background and Introduction

An important function of a medicine regulatory authority involves ensuring that medicines in circulation in the country are safe, efficacious and of good quality. The quality of medicines determines their effectiveness and safety and, hence, the health outcome of the patient. If the quality of medicines is compromised, investments in pharmaceutical commodities, health systems and pharmaceutical management systems are negated. The Pharmacy and Poisons Board (PPB) is the National Medicine Regulatory Authority established in 1957 by an Act of parliament, the Pharmacy and Poisons Act, Cap 244 of the Laws of Kenya. The PPB is charged with the responsibility of regulating the practice of pharmacy and trade in drugs. The PPB's core mandate is to ensure the provision of quality, safe and efficacious pharmaceutical products and services. This is done through evaluation and registration of pharmaceutical products, promotion of rational use of drugs, inspection and surveillance activities, licensing of personnel and institutions, clinical research authorization and advising the Government on any matter relating to regulation of drugs and poisons. Registration of medicines requires thorough quality control testing in order to ensure that the product meets quality specifications.

The National Quality Control laboratory (NQCL) was established in 1992 as a body corporate under the Pharmacy and Poisons (Amendments) Act, Cap 244. The laboratory serves as the technical arm of PPB and is mandated by the Act, under section 35B as a testing facility for pharmaceuticals and medical devices. Post Market Surveillance (PMS) requires collaboration and coordination of activities between the Pharmacy and Poisons Board, the quality control laboratory and various disease programs including Division of Malaria Control (DoMC), National AIDS and STI Control Program (NASCOP) and Division of Leprosy, TB & Lung Disease (DLTLD) amongst a broader spectrum of stakeholders and partners. A primary strategic objective of the Ministry of Medical Services (MOMs) is to ensure effective case management strategies in the field and this requires testing the quality and monitoring the effectiveness and safety of medicines and medical devices. Thus, post market surveillance is critical in ensuring that medicines and medical devices in the Kenyan market meet specifications for quality, safety and efficacy.
The information is used for: Injury prevention, Development of standards, Regulatory purposes and Product improvement.

Within the last few decades, there has been a growing global increase in public awareness and safety concerns related to:
- Substandard medicines
- Medication errors
- Lack of efficacy reports

- Use of medicines for indications that are not approved and for which there is inadequate scientific basis
- Case reports of acute and chronic poisoning
- Assessment of drug-related mortality
- Abuse and misuse of medicines
- Adverse interactions of medicines with chemicals, other medicines, and food
- Counterfeit medicines and medical devices

In the recent past, there have been many reports in the media pertaining to 'fake' and poor quality medicines circulating in the Kenyan market. Moreover, many unregistered and suspected counterfeit packs have also been reported to the PPB by brand owners or have been detected during PPB's post market surveillance (PMS) and routine inspections. Products that are mostly targeted for counterfeiting include high value products, products that are easy to make and products with high demand. Consequently there is urgent need for a strong PMS system in Kenya to address the above issues.

A study on antimalarials (study title: Antimalarial Medicines in Kenya, 2007) conducted by the Pharmacy and Poisons Board, Department of Pharmacovigilance, found that of the products sampled, 42.6% were not registered with most of them being manufactured in Kenya and India. These findings are not be limited to antimalarials only and therefore it is necessary to establish the registration status of all other products in the market.

Post market surveillance encompasses the **pro-active** and **reactive** collection of information on quality, safety and performance of Medicines, Medical Devices, Complementary medicines, Cosmetics, and related products after they have been released into the market (post-registration).

The use of ineffective, poor quality and harmful medicines can result in therapeutic failure, exacerbation of disease, resistance to medicines and also death. It also undermines confidence in health systems, health professionals, pharmaceutical manufacturers and distributors. Money spent on ineffective, poor quality medicines is wasted - whether by consumers or Governments.

Regulation of prescription and non-prescription drugs is critically important in protecting the health and safety of citizens. However approval process for medicines cannot adequately predict the full extent of harmful or unexpected effects of a medicine once it is on the market. Consequently, a post-market surveillance system is necessary.

The establishment of a PMS system is also in line with the Second National health Sector Strategic Plan's (NHSSP II) objective of enhancing the regulatory capacity of the Ministry of Health. Such a system will be able to detect harmful and unexpected effects of medicines and devices in a timely manner to avoid delay in follow-up and intervention measures. It also helps to improve the protection of health and safety of patients and users by reducing the likelihood of the same type of adverse incident being repeated in different places at different times. Thus greater consumer involvement will considerably

Appendix I

Sample collection form

Serial number: _____

Name of location/place where sample was taken:
.....

.....

.....

Address (with telephone and fax number, if applicable):

.....

.....

Date of sampling: .....

Names of people who took samples:
1. .....

2. .....

Product name of the sample: .....

Name of (active) starting material (INN, generic or scientific name)
with dosage strength: .....

Dosage form (tablet, capsule, etc.): .....

Batch/lot number: .....

Date of manufacture:..... Expiry date: .....

Registration or licence number (if applicable): .....

Name of the manufacturer: .....

Number of sample unit taken (tablet, capsule, etc):
.....

Storage conditions:.....
.....

9.0 Key Documents

Appendix i - Sample collection form
Appendix ii - Sampling guidelines
Appendix iii - Quality Reporting Form
Appendix iv - Laboratory analysis request form

improve the effectiveness of the post-market surveillance system. This will also lead to improved quality of medicines circulating in the Kenyan market.

Kenya's healthcare services have traditionally been delivered through dispensaries and health centers, complemented by district, provincial and national level hospitals. In an attempt to define the minimum human resource requirement, infrastructure and commodities, the NHSSP II specifies six levels of the healthcare system (level 1 to 6). Each level has both service delivery and management functions to ensure effectiveness. Throughout the process, the health of the nation is the prime focus and the driving force. This PMS strategy has been built and strengthened along the existing health system structures in the public and private sector including NGOs. The vision of the Pharmacy and Poisons Board is to be a global leader in the control and regulation of drugs, food supplements, cosmetics, complementary medicines, medical devices, poisons and the practice of pharmacy. The mission is to improve the quality of life of Kenyans by ensuring provision of quality, safe and efficacious pharmaceutical and related products. Hence the development of a PMS strategy is in line with this vision and mission.

The Pharmacy and Poisons Board has the responsibility of carrying out regular audits of the pharmaceutical products, medical devices, cosmetics, poisons and complementary medicines to ensure compliance with legal, quality and safety requirements.

1.1 Overview of medicines supply

Medicines play an important role in saving and prolonging lives and drawing people to health facilities, where they can also receive preventive treatment. In general, medicines are given to reduce the suffering and also the cost of health. In Kenya, there are over 10,000 (ten thousand) registered products. These products are either manufactured locally or imported. Currently, most of the drugs in the Kenyan market are imported from the Indian subcontinent

The supply chain to hospitals and pharmaceutical retail outlets is mainly through distributors. The public sector is served by the Kenya Medical Supplies Agency (KEMSA) while mission hospitals and some NGO health facilities get their supplies through the Mission for Essential Drugs and Supplies (MEDS). Retail pharmaceutical outlets and level 2 and 3 health facilities supply drugs to a majority of Kenyans.

1.2 Disease patterns

Diseases patterns have changed generally based on either environmental influence, changed feeding habits, emergence of new or discovered diseases and re-emergence of other diseases as a consequence of other diseases or syndromes. Medicines used in management of these diseases should always be of high quality to ensure successful therapeutic outcomes.

2.0 Objective of PMS

The primary objective of the post market surveillance system is to ensure safety of medicines and conformity with the accepted product specifications as declared in the

registration dossier. It will provide regular information on the quality of medicines circulating in the country.

2.1 Specific Objectives

The specific objectives that will be met under the post-marketing surveillance activities include the following:

1. To combat the spread of counterfeits/substandard medicines in Kenya
2. To obtain information on the quality of registered products in circulation
3. To determine the registration status of the products in the market
4. To develop a medicine information databank on quality of medicines in circulation
5. To disseminate information on quality of medicines to stakeholders involved in medicines procurement, use and regulation.
6. To promote communication and cooperation between stakeholders and partners involved in medicines procurement, use and regulation.

3.0 Scope

The Pharmacy and Poisons is charged with the responsibility of regulating medicines from clinical trial phase through to post-marketing phase. The Department of Pharmacovigilance will coordinate all post-market surveillance activities. The Department of Pharmacovigilance will work together with the Pharmaceutical Inspectorate Department, the Drug Registration Department and other departments as necessary.

Pharmacy practitioners and other healthcare workers shall spearhead the process of carrying out patient and public awareness of possible poor quality or defective pharmaceutical products, cosmetics and medical devices and develop a culture of reporting such defects/cases as an essential part of PMS system. Staff involved in pharmaceutical inspectorate activities shall provide an essential link in detection of such products at the periphery of the health care systems

The information gathered shall form a basis of determining the PMS activity in terms of frequency and scope. Feedback and regular updates shall be provided to the stakeholders without undue delay. These may include the general public, relevant ministries and other government departments, the pharmaceutical industry, healthcare workers, professional associations and other regulatory authorities among many. Post -Market Surveillance information is used for: Injury prevention, Development of standards, Regulatory purposes and Product improvement.

3.1 Medicines to survey

Poor quality or substandard medicines and counterfeit pharmaceutical products all have a direct and huge effect on disease burden. Doctors may diagnose correctly and prescribe the right drug, pharmacists may dispense the right drug and nurses may administer the right drug. However, if the quality of the ‘medicine’ is not as good, the patient may not

8.2 Financing Options

As a core function of the regulatory authority, this function will be financed through government funds allocated to the PPB. In addition, relevant public health programs (e.g. malaria, HIV/AIDS, DVI, TB and reproductive health) will be encouraged to provide supplementary funds for this activity through their respective budgets. Also in line with the health sector SWAP, development partners will be encouraged to support the program, either through direct funding to PPB, laboratory or through the relevant public health programs.

Private sector will also be encouraged to support and develop PMS programs for their products.

7.0 Regulatory Action

The objective of post market surveillance is to determine the quality of medicines and adherence to the legally set standards. Every post-market surveillance report will contain a summary of the results and recommendations.

Upon receipt of the report, the Board shall institute necessary legal actions to protect the public from further harm and improve the quality of products in the market.

The regulatory actions will include but not limited to;

- Withdrawal of affected products
- Recall of affected batches
- De-registration of affected products
- Prosecution of offenders
- Institution of disciplinary proceedings as per Cap 244
- Batch testing before releasing a product into the market
- Any other necessary legal action

8.0 Costs & Financing

8.1 Key Cost Elements

The cost elements for a post market surveillance activity include but not limited to

- Administrative Costs (PPB)
- Protocol development
- Training of data collectors
- Travel Costs – for field work
- Purchase of samples
- Transportation of samples for Laboratory testing
- Report writing
- Regulatory action

respond as expected, not respond at all or even get worse. This adds onto the overall cost of therapy and the financial burden to the patient, society and the healthcare programs at large, is significant. Keeping in mind the Millennium Development Goals (MDGs) that Kenya has committed to and the importance of availing the appropriate quality of medicines to all Kenyans, there is need to analyse all pharmaceutical products from time to time.

The selections of medicines to be surveyed include:

- Medicines that are of prime importance to public health programs such as, but not limited to anti-retroviral, anti-malarial and anti-tubercular drugs
- Medicines for chronic or life-threatening illnesses such as anti-diabetic, anti-hypertensive and anti-asthmatic drugs
- Medicines used for reproductive health
- Medicines for pediatric use
- Medicines that are potentially dangerous, unstable, difficult to formulate
- susceptible to counterfeiting
- Medicines from unregulated or poorly regulated markets
- Suspected products, products with complaints and suspicious products
- Products where previous findings indicated poor quality.
- The scope of this strategy shall be the entire range of medicines available in Kenya. Selection and determination of what is to be covered will be determined according to PPB's PMS prioritization criteria.

3.2 Main Activities

Post market surveillance will involve;

1. Collection of samples for selected medicines from the public, private, NGO and informal sectors as per protocol or in response to complaints
2. Testing of sampled medicines in accredited laboratories where necessary
3. Writing of reports for each activity
4. Adoption of reports by PPB
5. Implementation of corrective and preventive actions (CAPAs) as necessary
6. Follow up on the recommendations of each report

3.4 Coverage:

The coverage of PMS will be countrywide.

3.4.1 Geographical coverage

The four main sector facilities in Kenya include the public sector, the private sector, the mission/NGO sector and the informal sector (including shops, kiosks, dukas and supermarkets). Different sector facilities shall be used to survey medicines. These may, as and when required, be:

1. Nation-wide survey including all sectors
2. Public sector facilities alone
3. Private sector facilities alone
4. Mission/NGO facilities alone
5. Informal sector outlets alone or
6. A combination of any of the above

3.4.2 Facility types

The different facility types in the sectors include:

- Health facilities-(at all levels)
- Wholesalers, distributors and retail outlets
- Ports of entry and exit- such as the airports and sea ports
- Main procurement agencies- warehouses and regional stores

4.0 Roles and Responsibilities

The maintenance and enhancement of health and safety is a responsibility that is shared between government, industry, consumers, healthcare professionals and their respective associations. The key stakeholders in post-market surveillance include

- Patients/ Public
- Pharmacy practitioners and other healthcare workers
- Pharmaceutical Industries
- Programs in the Ministries of Health
- Private and Public Procurement and Distribution Agencies
- Testing facilities
- Regulatory bodies
- Professional organizations such as PSK, KPA, Medical Board, Nursing Council, etc
- NGOs
- WHO

Other stakeholders and partners

4.1 Responsibilities of Stakeholders

The stakeholders involved include:

5.4 Preparation of report

The study proposal will define the process of report writing.

6.0 Sample Testing

6.1 Quality Control Testing

- The specific tests to be carried out will depend on the products collected and the specific objectives of the study. These will include:
- in-house specifications especially for innovator products
- Full or selected tests as per Pharmacopoeia Standards
- Methods validated by the laboratory

An official monograph will be used whenever available

6.2 Full or selected test

The choice of scope of test(s) to be performed shall be controlled by the query posed. If sample is unknown or identity is doubted, a full monograph will be considered whereas samples whose query is limited to purity, dissolution, or sterility tests shall be limited to query area.

6.3 Pharmacopoeia Standard

The pharmacopoeia to be used shall be WHO recognized and/or validated method of analysis for new molecules.
The following monographs shall be used unless otherwise

- British Pharmacopoeia (BP)
- European Pharmacopoeia (Ph Eur)
- United States Pharmacopoeia (USP)
- International Pharmacopoeia

Others that may be recognized by the Board

The reference Standards to be used will be primary standards and/or standards whose purity has been ascertained against a primary standard.

6.4 Laboratory Analysis

The National Quality control Laboratory will be the main Laboratory for all tests (unless where the Laboratory has no Capacity). Any other WHO prequalified Laboratory may be contracted as required.

- The extent to which the quality of the product has been assessed prior to registration
- The capacity of national quality laboratory and other accredited laboratories
- The extent to which the requirements for GMP are implemented; and
- The number of products that are present in the market.

The sampling frequency may be different for different products. It is proposed that medicines be assessed regularly (every 2-3 years). Suspect products, products for which complaints have been received or products where previous findings indicated poor quality- whether survey was carried out by the PPB or other institutions- will be surveyed at earliest opportunity. Such products will also be subject of investigation by the Board.

5.3.3 Sample Transportation and Documentation

Samples will be appropriately coded during collection at the site and sent to the PPB. Adequate care and measures will be taken to ensure that samples reach the site where the tests are to be performed without any physical damage or degradation.

5.3.4 Handling and Storage of Samples

Samples collected from the field will be sent to PPB offices via a courier, registered parcel, delivered by the data collector or by any other appropriate method.

The coordinator of the study at PPB will receive and verify the details of the samples as per the sample collection form. The samples will then be stored in an area clearly marked for that purpose which must be lockable. Thermolabile products will be stored in a refrigerator or as per the storage conditions. The study coordinator will, at the earliest opportunity dispatch samples to the laboratory for testing and make follow-up on the progress of analysis.

4.1.1 Pharmacy & Poisons Board

Has primary responsibility to enforce compliance

- Core mandate is to ensure the provision of quality, safe and efficacious pharmaceutical products and services to the public
- Coordinate sample collection from each site (via formal letters, phone calls, etc)
- Forward samples to the testing laboratory together with testing instructions
- Receipt and evaluation of analytical results from testing laboratories Verification of results of non-conforming samples
- Facilitate collection of more samples if necessary as part of PMS strategy
- Take action as appropriate. In the case of non-conformity with specifications, PPB can impose sanctions as defined in law:
- issue product recall if deemed necessary to protect public health,
- Reprimand manufacturers, importers, distributors, wholesalers, retailers and pharmaceutical representatives. These actions will be determined and taken on a case by case basis.
- Gathering all information for writing the report
- Disseminate the report of PMS to all stakeholders.
- Present summary of results to relevant authorities

4.1.2 NQCL and other accredited laboratories

Examination and testing of samples received from sites

- Submit the results to study coordinator with a summary of analysis done.
- Study coordinator may request additional testing if needed (non-conforming samples)
- Study coordinator will work closely with NQCL or any other accredited testing laboratories during re-sampling if more testing is required
- Store retained samples for reference and future use as required by PPB

4.1.3 Public Health Programs

In collaboration and consultation with PPB and NQCL:

- Develop PMS budget
- Provide travel logistics including transportation to and within the sites
- Oversee the PMS activities at the sampling the sites
- Support data collection teams in gathering all samples from sites and ensure their delivery to PPB
- Provide the list of samples to be collected
- Preparation of sampling strategies (number of samples per site/ sector / source)
- Provide funds for testing of samples at the laboratories
- Liaise with PPB and other partners when necessary

- Share the results with stakeholders

4.1.4 Development Partners

- Participate in the discussion and dissemination of results
- Provide technical and financial assistance in the implementation of PMS activities
- Ensure follow-up, monitoring, evaluation, and execution of PMS activities as per the budget
- Provide training as needed
- Disseminate results

4.1.5Procurement Agencies

- Provide samples available to sampling team
- Provide samples to health facilities to replenish withdrawn samples if necessary
- Participate in discussion on findings and implementation of regulatory action as directed by PPB

4.1.6 Study Coordinator/Department of Pharmacovigilance at PPB

The coordinator will be in charge of:

- Coordinating the PMS activities
- Ensure the development of a sampling and analysis plan;
- Supervise the implementation of the sampling strategies and the sample collection;
- Ensure that samples are analyzed according to the protocol;
- Ensure that testing results are analyzed accordingly;
- Write and disseminate the report; and
- Handle any other issues that may arise during the study period

Key institutions and departments that may be working closely in carrying out routine post-market surveillance activities include, but are not limited to:

- The Ministries of Health
- The National Quality Control Laboratory (NQCL)
- Other accredited testing laboratories
- Procurement Agencies
- National Public Health Programs
- Other development partners and stakeholders include,
- The Academia
- PSK and KPA

4.1.7 Technical Committee on Post Market Surveillance

Study specific questionnaires and sample collection forms may be used to collect information that may be necessary to establish the quality of a pharmaceutical product, medicinal device or a biological product.

5.2.3Interviews and Observation

Where necessary, the information collected may be verified through interviews, observation or any other suitable method.

5.3 Sampling

5.3.1Sampling Strategy

A defined number of selected products will be sampled from identified sites. The sample size will be as per PPB guidelines on sampling and the specific requirements of the protocol or the activity being undertaken. For purposes of analysis, units of one sample must be of the same batch or the same dispensing container. The sampling plan shall be as representative and inclusive as possible.

All the sectors, levels of healthcare and regions will be considered as per the study design.

Unless otherwise stated, the sampling will be on random basis. However, purposeful sampling may be done when necessary. The remaining shelf-life of samples to be collected shall be defined in the specific study proposals.

Samples will be collected as per PPB guidelines for sampling and in consideration of the sampling plan outlined in the study proposal.

Before starting the survey, appropriate arrangement with NQCL or any other approved laboratory which will perform testing of products will be done.

5.3.2 Frequency of sampling

` The extent, to which routine surveillance will be undertaken, as opposed to assessment of products, will depend upon factors such as:

3.The variables and end points that will be used to answer the surveillance questions e.g. Quality Parameters, etc

4. The surveillance approach or methodology to be used.

5. Sample size and units of observation

6. The investigator agreement, if applicable

7. Source of data e.g. registration dossiers, hospitals records etc.

8. The data collection plan and tools

9. The procedure for monitoring conduct and progress of surveillance

10. An estimation of the duration of surveillance

11. All data analyses and statistical tests planned.

12. The content and timing of reports

5.1.3 Designated person information

i. Name, address and telephone number

ii. Qualification and Experience

iii. Sponsor

iv. Declaration

5.2 Tools for Data Collection

5.2.1 Reporting Poor Quality Medicinal Products

The form for reporting poor quality medicinal products will be used for spontaneous reporting of suspected poor quality medicinal products. It will be distributed through the district pharmacy facilitators (DPF), to all health facilities. Completed forms will be sent to PPB head office, Nairobi, attention department of Pharmacovigilance preferably through the DPF. The reporter may be asked to send a sample of the suspected product for further evaluation and analysis.

Forms will be available through PPB office, District Pharmacist, and PPB website.

5.2.2 Questionnaires and Sample collection forms

The technical committee on post- market surveillance will be based at the Pharmacovigilance department, Pharmacy & Poisons Board and will include experts from any of the following fields of specialization among others:

- Pharmaceutical analyst
- Clinical Pharmacologist/ Pharmacist
- Regulatory pharmacist
- Medical specialists such as Physician/Obstetrician/ Pediatrician/ Surgeon/ Veterinary Surgeon
- Statistician
- Public health specialist

The main functions of technical committee on post- market surveillance will include, but not limited to:

1. Assessment and approval of PMS plans / proposals before being rolled out
2. Monitoring and evaluation of PMS activities.
3. Release of study Reports to the public, industries, MOH Departments/ programs and other stakeholders
4. Recommending necessary regulatory actions to the Board

4.1.8 Pharmacy practitioners and other healthcare workers

Patient and public awareness of possible poor quality or defects of pharmaceutical products and medical devices and development of a culture to report such defects will be essential for any PMS system. Staff involved in the drug distribution chain will provide an essential link in the detection of pharmaceutical products defects at the periphery of the distribution chain and healthcare system.

Pharmacy practitioners and healthcare workers roles in the PMS system include

1. Patient/public education
2. Detection and reporting of pharmaceutical defects
3. Proper documentation of defects detected
4. Investigation, where necessary
5. Patient feed back

4.1.9 District/Provincial Pharmacist

1. Will carry out investigations including sampling and receiving reports from pharmacy outlets and send the reports/ samples from the Districts to the PPB zonal offices on a weekly, monthly basis or on ad hoc basis as the case may be.
2. May facilitate PMS investigation initiated by PPB or any other authorized players.
3. Will be the principal investigator within the District and will coordinate a team comprising of Pharmacists, Pharmaceutical Technologists, clinicians and nurses as the case may demand from time to time.

4.1.10 Zone office

1. Every zonal office will fall under the immediate supervision of a provincial Pharmacist
2. This will be responsible for
   - Supervision of District Pharmacy Facilitator
   - Training of staff involved in PMS activities.
3. The Provincial Pharmacist will be the zonal team coordinator and will coordinate the investigation, report to the PPB and contribute to public education on medicine appropriate use, and on safety and quality issues.
4. The zonal team will
   1. Combine reports from the districts concerned into one.
   2. Ensure appropriate labeling, storage and transportation of the samples to the testing facilities and PPB
   3. Provide relevant reports to the PPB
   4. The findings of the investigation and the conclusions of the Expert Review Panel and Regulatory Actions to be taken will be fed back to patients/ public by the zonal team coordinator or other designated individual.

4.1.11 Patients /Public

Patients and the general public are to report any safety concerns and unacceptable, unexpected or suspected poor quality medicines, food supplements, cosmetics or medical devices dispensed to them to the Pharmacy & Poisons Board. It is

also the responsibility of the patient and members of the public to procure medicine from regulated outlets and report any suspected malpractices to the Board.

Each of these has an important role to play and responsibility to bear.

(Draw structure of operations on how to link the stakeholders)

5.0 Post-Market Surveillance Plan

The design to be used in post market surveillance will depend on the objectives of the study, which must be clearly defined in the study proposal. Any specific concerns to be investigated should be identified and explicitly addressed by the proposed methods of data collection and analysis.

5.1 Contents of PMS Proposal

Post market surveillance proposal shall contain the following details:

5.1.1 Organization/administrative information

- Name and address of the manufacturer
- Name (brand and generic) of the products
- Name and address of the contact person for the submission
- Pre-market application/submission/registered numbers for the product(s)
- Table of contents identifying the page numbers for each section of submission.
- Description of the product (refer to registration dossiers)
- Product codes
- Indications for use and claims for the product

5.1.2. Post Market Surveillance plan

1. Objectives of the surveillance exercise
2. Subject of the study e.g. medicine, medical device, biological product, etc