

**TANZANIA MEDICINES AND MEDICAL DEVICES
AUTHORITY**



**GUIDELINES FOR DEVELOPING AND
IMPLEMENTING MEDICINES POST MARKETING
SURVEILLANCE PROGRAMME**

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Foreword

Post Marketing Surveillance (PMS) refers to practice of monitoring quality, safety and efficacy of medicines after they have been registered and released on the market. Presence of poor quality, unsafe and ineffective medicines on the market resulting from inadequate enforcement, existence of unofficial ports of entry, unscrupulous dealers, inadequate cooperation and support from other law enforcement agencies and failure of manufacturers to comply with cGMP requirements may pose risks to public health and consequent lead to significant increase in morbidity and mortality.

Ministry of Health, Community Development, Gender, Elderly and Children, through the Tanzania Medicines and Medical Devices Authority (TMDA) has been implementing its regulatory strategies aiming at ensuring that medicines which are circulating and used in Tanzania Mainland are of good quality, safe and efficacious in order to protect and promote the public health. One of the strategies is existence of structured PMS Programme which is designed to monitor quality and safety of selected registered medicines on the market.

Since the establishment of surveillance system through structured PMS Programme a number of counterfeit and substandard medicines have been encountered

from the market and necessary regulatory actions taken. Nevertheless quality surveillance of medicines had never received the required attention due to lack of comprehensive guidance on methodology to be employed during designing and implementation, hence increased probability of counterfeit and substandard medicines to penetrate into the market.

To address this TMDA has established guidelines for developing and implementing PMS Programme in Tanzania Mainland. The guidelines outline the steps to be considered during preparation and execution of PMS Programme. The use of these guidelines is expected to activate effective PMS activities aiming at improving quality data that would provide confidence to assure the public and other stakeholders on quality, safety and effective of medicines circulating on the market. The guidelines are intended to be used by all stakeholders in medicines regulations and the Authority as key implementer.



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Acknowledgement

This guideline has been developed following the need of developing and implementing post marketing surveillance programme. The guideline outlines the key factors to be considered during developing a PMS Programme and its implementation.

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Abbreviations

BP	-	British Pharmacopoeia
cGMP	-	Current Good Manufacturing Practices
CoA	-	Certificate of Analysis
DBS	-	Directorate of Business Support
DG	-	Director General
DLS	-	Directorate of Laboratory Services
DMC	-	Directorate of Medical Products Control
EAC	-	East African Community
MoHCDGEC	-	Ministry of Health, Community Development, Gender, Elderly and Children
NGOs	-	Non-Government Organizations
OTCs	-	Over the counter medicines
PMS	-	Post Marketing Surveillance
Ph Eur	-	European Pharmacopoeia
Ph.Int	-	International Pharmacopoeia
PV	-	Pharmacovigilance

SADC	-	Southern African Development Community
SF	-	Sub-standard/ Falsified
SOP	-	Standard Operating Procedure
SWOC	-	Strength/ Weakness/ Opportunities/ Constrains
TB	-	Tuberculosis
TLC	-	Thin Layer Chromatography
TMDA	-	Tanzania Medicines and Medical Devices Authority
USP	-	United States Pharmacopoeia
WHO	-	World Health Organization

Definition of terms

“Batch number” means distinctive combination of numbers and/or letters which uniquely identifies a batch on the labels, its batch records and corresponding certificates of analysis.

“Medicines” means human medicines, veterinary medicines, herbal medicines, antiseptics and disinfectants.

“OTC medicine” means medicine available to the public without a prescription

“Pharmacovigilance” is part of post marketing surveillance that involves science and activities relating to the detection, assessment, understanding and prevention of adverse events or any other medicine related problems.

“Post marketing surveillance” means clinical trial or other investigations usually conducted under a single protocol to gather specific information about an approved medicinal or biological product.

“Risk assessment” means identifying and characterizing the nature, frequency, and severity of the risks associated with the use of a product. Risk assessment occurs throughout a product’s lifecycle, from the early identification of a product as a candidate, through

the pre-marketing development process, and after marketing.

“Sample” means number of units (i.e. same product name, manufacturer, dosage form, package size, packaging material and strength) representing the same batch and collected at the same location/outlet.

“Sampling” means is the process of selecting units (e.g., batch, people, organizations) from a population of interest so that by studying the sample we may fairly generalize our results back to the population from which they were chosen.

1. INTRODUCTION

1.1 Background

All regulatory systems recognize the importance of quality medicines due to the fact that there are several factors that may lead medicines not comply with quality requirements and specifications. Those factors may include manufacturing processes, transportation, storage, distribution, handling and dispensing to patients.

During the period of development medicines are tested for short-term safety and efficacy at a limited duration to a limited number of carefully selected individuals who have been “controlled” for this purpose. There are therefore risks after medicines have been released on the market result into adverse effects to the population. This is due to the fact that upon approval medicines are used in real-life scenarios as opposed to controlled settings of pre-marketing trials where study conditions are tightly controlled.

Our Country depends on approximately 85% imported medicines due to inadequate capacity of domestic manufacturing plants. There is thus another risk of having substandard and/or falsified medicines (SF) on the market due to lack of instant oversight of manufacturing activities of overseas plants. These risks and others necessitated the existence of surveillance

system to continuously monitor quality, safety and effectiveness of medicines circulating on the market.

TMDA has developed these guidelines to guide the implementers and other stakeholders in medicines supply chain on how to prepare and implement a well structured PMS programme that will focus on monitoring quality and safety of registered medicines on our market. They provide recommendations and examples of various methodological approaches with a discussion of their advantages and disadvantages, and suggestions on preparation of reports on the results obtained from such programme.

Adherence to these guidelines may lead to effective and functional surveillance system that will provide assurance on the quality and safety of medicines circulating on the market. It may also lead to existence of cost effective Programme that will consider value for money during implementation.

1.2 Rationale

Good quality, safe and efficacious medicines make an important contribution to global reduction in morbidity and mortality as they are essential for efficient disease management. To ensure that medicines that are available to patients are of good quality, safe and efficacious the Authority applies various regulatory functions which include:

- a) Authorization/registration for marketing following the assessment of product documentation, inspection to ascertain manufacturers' compliance with cGMP principles and approval of product information;
- b) Post marketing surveillance activities including maintenance of products' authorization and/or registration through variations or renewals, regular inspections of manufacturers, importers, distributors, wholesalers and retailers, quality control testing and pharmacovigilance;
- c) Implementation of regulatory actions in the event of any quality, safety and efficacy problem being found.

Post Marketing Surveillance Programme may serve as a source of information about quality of medicines available to patients however the accuracy, reliability and interpretation of the data obtained depend on its design, organization of sample collection and available resources, testing and evaluation of data. Properly collected, interpreted and used relevant data are also vital for the planning of effective interventions and strategies to improve the quality, safety and efficacy of medicines on the market.

Medicines post marketing surveillance activities are costly and limitations on resources may restrict the number of samples to collected, parameters tested,

techniques to be used for analysis or number of staff available to conduct the surveillance and analysis. Therefore it is important to optimize use of resources by focusing on those medicines and parameters that pose a higher risk to patients and apply risk analysis during planning.

Existence of a well structure and designed Post Marketing Surveillance Programme depends on availability and adherence to a proper guiding tool. There is therefore an importance to establish guidelines for developing and implementing such programme to cater different category of medicines based on risks. Implementation of well designed programme may not only triggers cooperation with partners and joint organization of surveys in several countries but also enable the Authority to confidently share testing capacities, experience and information learnt from effective surveillances.

1.3 Objectives of the Guidelines

The main objective of these guidelines is to provide practical guidance to TMDA in developing and effectively implementing Post Marketing Surveillance Programme.

2. DEVELOPING AND IMPLEMENTING PMS PROGRAMME

In principle PMS Programme should be organized such that can be able to assess the quality of medicines provided to patients and generate the data that can help to formulate strategies and plans to ensure provision of good quality medicines. The programme should be well organized and implemented to confirm that patients are receiving satisfactory medicines and give reassurance that the regulatory system is functional. Thus when developing PMS programme the following should be considered:

2.1 Objectives of PMS Programme

Detailed objectives must be set since all the activities and requirements of the programme will be derived from the objectives. The objectives should reflect reasons why PMS is conducted and should be formulated in a way that enables identification of medicines to be involved, sample collection sites, areas or regions to be covered and tests to be conducted.

2.1.1 Broad Objective

There is a wide range of possible objectives to be set. Few examples are given below to serve as guidance:

- a) To assess quality and safety of medicines on the market and conformity with acceptable specifications as declared in the registration dossiers.

- b) To evaluate the quality of selected medicines available in the market in selected areas or regions at various levels of the distribution/supply chain with the aim of assessing the exposure of patients to poor-quality medicines and proposing appropriate actions;
- c) To evaluate the quality of specific medicines used in the treatment programme;
- d) To compare the quality of domestically produced and imported medicines in order to recommend appropriate regulatory actions and adjust pharmaceutical policy;
- e) To identify possible causes of inferior quality of specific products to which patients are exposed and to propose possible strategies and implementation plans to address the problems identified by the survey;
- f) To test the quality of selected medicines in order to support the Authority in identification of manufacturers that are not in compliance with quality standards and regulatory measures;
- g) to find out if, within a selected category of medicines, any spurious/falsefully labeled/falsified/counterfeit (SFFC) products have penetrated the market in selected areas or regions, what the possible health impacts may be for patients, and to propose possible strategies and implementation plans to prevent harm to patients.

2.1.2 Specific Objectives

In addition to a broad objective, specific objectives may be set in the PMS Programme depending on required information. Examples of the specific objectives may include the following:

- a) To combat the spread of counterfeit/substandard medicines on Tanzania Mainland.
- b) To obtain information on quality of registered products in circulation.
- c) To determine registration status of products on the market.
- d) To develop medicines information databank on quality of medicines in circulation.
- e) To disseminate information on quality of registered medicines to stakeholders involved in medicines supply chain.
- f) To promote communication and cooperation between stakeholders and partners involved in medicines supply chain.
- g) To identify possible causes of inferior quality of specific products to which patients are exposed.

2.1.3 Surveillance Questions

To ensure that PMS Programme provides the necessary information it is also essential in addition to a primary objective and specific objectives, to set appropriate and relevant questions to be addressed during implementation. Some examples of such questions include:

- a) What proportion of sampled medicines fails quality testing?
- b) What proportions of sampled medicines fail quality testing at different levels of the regulated distribution chain and in the informal market?
- c) What proportions of medicines sampled from different geographical regions fail quality testing?
- d) What proportions of sampled domestically produced and imported medicines fail quality testing?
- e) Which specific quality tests do the selected medicines fail?
- f) Are any of the deficiencies critical, i.e. could they substantially affect treatment efficiency and/or cause harm to patients?
- g) Are there treatment failures related to a specific disease, which can be associated with low-quality medicines?

- h) What is the registration status of the sampled products and what proportions of registered and unregistered products fail quality testing?
- i) What are the supply chains by which poor-quality medicines are distributed and what are the market segments they serve?
- j) Are there any indicators of poor storage and distribution conditions that influence quality of sampled medicines?
- k) Are there poor-quality medicines in the selected area, e.g. at the port of entry?
- l) What is the proportion of poor-quality medicines being sold and/ or the proportion of pharmaceutical outlets selling poor-quality medicines in a particular area?
- m) Does the proportion of poor-quality medicines or the proportion of pharmaceutical outlets selling poor-quality medicines exceed a predetermined level?
- n) Has there been a change in the quality of a medicine or medicine category, or in an area (in the case of repeated random surveillance with consistent design)?

2.2 Scope and Applicability

TMDA is charged with the responsibility of regulating medicines from clinical trial phase to post-marketing surveillance phase. Medicines include both human and veterinary medicines, and they also include herbal medicines, biologicals, vaccines, blood and blood products and medical gases.

When developing the PMS Programme scope and applicability of programme should be clearly set. The Section of Clinical Trials Control and Pharmacovigilance will coordinate all post-marketing surveillance activities and will work together with the Medicines Inspectorate Section, Medicines Registration Section, Medicines Analysis section, Zonal Offices and other departments as may be necessary. In order to enable effective implementation of the programme, all key players should be described during planning and development.

2.3 Coverage

PMS Programme is intended to be implemented within Mainland Tanzania. Coverage should depend on the set objectives and may include certain districts and regions based on criteria set under these guidelines. Coverage may also include certain public, private and faith based organizations health facilities to include Manufacturers of medicines, importers and distributors, wholesale and retail pharmacies, Duka la Dawa Muhimu (DLDM), hospitals, health centers,

dispensaries and clinics. During development coverage should be stated in the PMS Programme.

2.4 Management and time frame

In order to have an effective implementation of PMS Programme it is very important for each responsible person to be involved and agree with the plan before it is implemented. Responsibilities and tasks of the people who have key roles in the programme should be identified at the beginning and should include those with the responsibility for monitoring the implementation, performing analysis, processing results and preparing the final report. Lines and means of communication should be agreed in advance.

Timing of sample collection is important since seasonal changes in environmental conditions may have an influence on the quality of the medicines collected. For instance that it is possible that falsified antimalarials are more common during malaria season or that access to outlets in rural areas may be impeded in the rainy season, for example as a result of floods or landslides.

Issues such as the use of the results and their public availability should be clearly understood by the responsible persons involved in the PMS from the beginning. Relevant regulatory measures should also be understood and appropriate time of implementation.

A publication plan including authorship of any papers to be submitted for peer-reviewed publication and a distribution list of those to whom the report will be disseminated should be agreed at the beginning of the PMS. Public release of data that might be considered confidential also needs to be understood among key players at initial stages. Furthermore it is important to plan the financial resources expected for the whole PMS before it commences.

2.5 Methodology

PMS activities shall be conducted according to a predefined programme and methodology. Inadequate instructions on the programme or noncompliance with the programme methodology, e.g. insufficient sample size, incorrect sampling and/or testing may lead to inaccurate results and policy recommendations. Careful consideration of the methodology should guide the PMS preparation and the people involved should comply with the instructions.

In principle, in addition to the background and explanation of the objectives PMS Programme should contain information on the following:

2.5.1 Identification and selection of medicines to be monitored

Identification and selection of medicines to be monitored is one of the most important steps in the preparation of PMS programme. Identification and selection shall be driven by the set objectives and public health considerations. The potential public health impact of poor-quality medicines should also be a key guide for selection. In either case the programme should indicate criteria used in identification and selection of medicines to be monitored.

During identification and selection the following should be considered:

- a) Source of information such as:
 - i. Experience from inspection activities, dossier assessment, laboratory analysis, pharmacovigilance activities, drug information or public health programmes;
 - ii. pharmacists and other health-care professionals;
 - i. Previous surveillance reports, published studies, scientific literatures;
 - ii. Customers' complaints;

- iii. Suppliers' performance;
 - iv. Importation data
 - v. List of registered medicines and unregistered medicines authorized under certain conditions (e.g donation)
- b) Set criteria which shall include but not limited to:
- i. Medicines that are used for treating diseases of economic importance such as anti-retroviral, anti-malarial and anti-tuberculosis;
 - ii. Medicines for diseases of common occurrence in the certain regions;
 - iii. Medicines for priority endemic diseases;
 - iv. Medicines for common chronic diseases or life-threatening illnesses such as anti-diabetics, anti-hypertensive and anti-asthmatics;
 - v. Medicines which have indicated poor quality performance;
 - vi. Medicines which are used by special group at risk such as children and pregnant women;

- vii. Medicines which are irrationally prescribed and dispensed;
- viii. Medicines which are prone to resistance due to non-adherence;
- ix. First line medicines with complicated dosage regimen;
- x. Medicines which require prolonged administration to a larger population and a number of them are used in combination;
- xi. Medicines that are candidates for possible counterfeiting; and
- xii. Medicines which are potentially dangerous, unstable or difficult to formulate.

2.5.2 Selection of areas or regions to be sampled

A number of different geographical areas should be sampled unless the objectives expressly justify targeting only one area. Samples should be collected in various locations, as situations in rural and suburban areas often differ. Depending on the survey objectives, the following criteria may be considered when selecting areas to be surveyed and should appear in the programme:

- a) population density;

- b) incidence or prevalence of the disease for which the target medicines are indicated;
- c) level of risk of poor-quality medicines, e.g. the risk may be higher along trade routes across country borders, in areas where poor quality medicines have been previously found, areas where formal health services are limited, and in areas where the NMRA has few or no resources to monitor the distribution of medicines;
- d) degree of urbanization;
- e) income level of the population in the target area;
- f) areas with complex distribution systems;
- g) areas with outlets selling predominantly unregistered and/or illegal medicines
- h) Regions and districts bordering other countries;
- i) Regions and districts that are not frequently inspected;
- j) Areas with high trends of quality problems (including major towns and centres);
- k) Areas with high prevalence of diseases related to products being monitored; and
- l) Regions and districts which are highly populated.

2.5.3 Types of sample collection sites

Pharmaceutical outlets shall be classed as public outlets (government) and private outlets (non government) which include NGO's and Faith Based Organizations. They shall also be classified according to their level in the supply chain as follows:

- a) Level 1 – points of entry to the market e.g. warehouses of pharmaceuticals importers or manufacturers, Medical Stores Department and other facilities supplied directly within various programme, pharmaceuticals wholesalers and/or distributors;
- b) Level 2 – pharmaceuticals wholesalers and/or distributors, retail pharmacies, DLDM and other regulated dispensing facilities, hospitals, health centers, dispensaries clinics, polyclinics and any other health facilities;
- c) Level 3 – informal outlets selling medicines outside the approved distribution system include street vendors.

During planning stage type of sample collection sites should be understood and reflected in the PMS Programme.

2.5.4 Sampling Plan

PMS Programme shall include a well designed sampling plan that contains information on name(s) of the samples to be collected; unit pack; number of unit pack per batch; quantity; cost; dosage form; strength; category; sampling sites(s); number of brands to be collected; and number of batches to be collected per each brand. The following should be taken into considered during preparation of sampling plan:

- a) Identification of sample collection sites (regions/ districts & levels as described in *section 2.5.3*);
- b) Include all medicinal products to be sampled;
- c) Samples to be taken close to the point of use of the products;
- d) Samples to be taken from each of the identified facilities (example Medical Stores Department, manufacturing facilities (if any), ports of entry, distribution outlets such as importers and wholesalers, pharmacies, hospitals, health centers, dispensaries and clinics);
- e) Define timeframe for sampling phase;
- f) Define and approve budget; and
- g) During planning, appropriate arrangement with laboratory or any other approved laboratory which will perform testing of products should be done.

2.5.5 Training of Sample Collectors

Documented standard procedures for training, sampling, sample handling and transportation should be available. To ensure successful implementation of PMS programme training must be provided at all implementation levels. Training will also include:

- a) Sampling planning, methodology and procedures;
- b) Screening techniques to include physical inspections, disintegration testing, color reaction and TLC interpretation;
- c) Reporting of results;
- d) Analysis of samples and interpretation of results; and
- e) Monitoring and evaluation of the programme

2.5.6 Sampling design

- a) Standard operating procedures must be in place
- b) Samples should be collected from different batches, different locations and from all available sectors to accurately represent the selected medicines. Sampling should be performed by trained sample collectors and should adhere to the approved sampling plan.
- c) Sampling site can be different from one region/ district to another depending on products to be sampled.

- d) Samples must be collected properly in their original containers or packages although any sample (s) which is not in its original container must also be collected as long as all information is recorded on the PMS sample collection form.
- e) Sampling tools required must be provided (Sampling bags, forms, marker pen, knives, Spoons etc) and resources.
- f) Samples should be packed and stored in a manner that prevents any deterioration, contamination or adulteration
- g) Samples should be stored in accordance with the manufacturers recommended storage conditions
- h) Adequate measures have to be taken to ensure that samples are transported to the laboratory in good conditions and should prevent any physical damage to the samples.

2.5.7 Sample screening and testing

2.5.7.1 Sample screening (product information review)

- a) Product information review and their package will help to give information about the manufacturing source, sample integrity and identification of counterfeit and spurious medicines.
- b) All physical samples and labels should be reviewed for conformity to appearance and labeling requirements.

- c) Examined against information provided in the respective dossier and sample submitted during registration process. e.g;
 - i. Oral solids are checked for spots, moulds, abrasions, colour, odour, shape etc
 - ii. Oral liquids are examined for container leakage, particles, homogeneity, tampering, fill volume, odour, colour etc
 - iii. Labels (primary and secondary) and package inserts are examined for information, size and type of container, format, shape, print, stickiness, legibility and indelibility.
- d) Information should be entered in the PIR form - one sample per one Product Information Review form.

2.5.7.2 Sample screening (simple basic tests)

- a) Simple disintegration test, color reaction test and Thin Layer Chromatography (TLC) should be conducted as per developed SOPs for screening and laboratory testing
- b) All samples should be subjected to screening testing

2.5.8 Laboratory Testing

- a) TMDA 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.
- b) All failed/doubtful and 10% of passed sample(s) should be subjected to confirmatory testing.
- c) The specific tests to be carried out will depend on the products collected and the specific objectives of the survey.
- d) An official monograph will be used whenever needed.
- e) 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:

- a) British Pharmacopoeia (BP)
- b) European Pharmacopoeia (Ph Eur)
- c) United States Pharmacopoeia (USP)
- d) International Pharmacopoeia and
- e) Any other that may be recognized by the Authority

2.6 Evaluating results and report preparation

- a) Results shall include information pertaining to samples collected, collection points, analytical tests and results obtained, review of approved summary of product characteristics, associated risk factors and potential reasons for failure of product's quality.
- b) The results should be evaluated by experts (including risk assessors and epidemiologists).
- c) Evaluation should include the statistical treatment of data, graphical presentations, trend analysis and indications of success or failure of the programme
- d) Report shall be prepared in line with approved reporting format.

2.7 Results dissemination

- a) Publication of report
- b) The information should be made available to the public e.g through reports, website, conference and when applicable in international journals.
- c) The information may also be shared with other regulatory agencies, WHO and harmonization initiatives – EAC and SADC

2.8 Enforcement

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

- b) The Authority should institute all necessary legal actions to protect the public. The enforcement will include but not limited to:
 - i. Withdraw of products
 - ii. Recall of batches
 - iii. De-registration of products
 - iv. Prosecution of offenders
 - v. Institution of disciplinary proceedings as per Law
 - vi. Any other necessary legal action(s)

2.9 Monitoring & Evaluation

Monitoring and Evaluation is important to assess programme effectiveness and performance. It will be conducted throughout the programme by an identified PMS Task Force using developed implementation monitoring tool.

2.10 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-marketing surveillance include:

- a) Patients/ Public
- b) Pharmacy practitioners and other healthcare workers
- c) Pharmaceutical Industries
- d) Programs in the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC)
- e) Private and Public Procurement and Distribution Agencies
- f) Development Partners
- g) Regulatory bodies
- h) Professional organizations such as Medical Board, Nursing Council, etc
- i) NGOs
- j) Other stakeholders and partners

Responsibilities of key players involved in PMS include:

Tanzania Medicines and Medical Devices Authority

Has primary responsibility to enforce compliance

- a) Core mandate is to ensure the provision of quality, safe and efficacious medicines to the public
- b) Coordinate sample collection from each site
- c) Laboratory testing
- d) Evaluation of analytical results
- e) Report writing for publication and dissemination of the PMS report to all stakeholders
- f) Take action as appropriate

In the case of non-conformity with specifications, TMDA can impose sanctions as defined in law.

Clinical Trial and Pharmacovigilance Section / PMS Coordinator at TMDA

The coordinator will be in charge of:

- a) Coordinating the PMS activities
- b) Ensure the development of a PMS Programme including sampling plan;

- c) Supervise the implementation of the Programme
- d) Ensure samples are collected as per plan
- e) Ensure that samples are analyzed accordingly
- f) Write and disseminate the report; and
- g) Handle any other issues that may arise during the implementation period

Post Marketing Surveillance Task Force

The PMS Task Force will be based at TMDA sub-office and will include experts from different Directorates;

- a) DLS (Drug analysts)
- b) DMC (Drug inspectors)
- c) DMC (Drug registration officers)
- d) DBS (Planning and marketing officers)
- e) DG's (Zonal Offices Coordinator)

Any of the following fields of specialization among others may be invited if necessary depending on the product monitored:

- a) Medical specialists
- b) Statistician
- c) Public health specialist
- d) Microbiologist
- e) Biotechnologist

The main functions of PMS Task force will include, but not limited to:

- a) Developing PMS programme and sampling plan
- b) Assessment of the Programme and sampling plans before being rolled out
- c) Oversee the implementation of PMS Programme
- d) Monitoring and evaluation of PMS activities
- e) Release of PMS Reports to the public, Industries, MOHCDGEC Departments/ programs and other stakeholders
- f) Recommending necessary regulatory actions to the Authority

Zonal Office will be responsible for

- a) Training of staff involved in PMS activities
- b) Carry out sampling as per proposed sampling plan
- c) Ensure appropriate labeling, storage and transportation of samples collected directly to TMDA Sub-office
- d) Provide relevant reports to the TMDA Sub-office

Public Health Programs

Provide authorization to data collection teams in gathering all samples from sites.

Development Partners

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

Procurement Agencies (Medical Store Department)

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

2.11 Costs & Financing

2.11.1 Key Cost Elements

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

- a) Administrative Costs (TMDA)
- b) Programme development
- c) Training of sample collectors
- d) Travel Costs – for field work

- e) Purchase of samples
- f) Transportation of samples for Laboratory testing
- g) Laboratory analysis
- h) Evaluation of results and report writing
- i) Regulatory action

2.11.2 Financing Options

As a core function of the regulatory authority, this function will be financed through government funds allocated to the TMDA. Development partners will be encouraged to support the program, either through direct funding to TMDA, laboratory or through the relevant public health programs.

3. STRUCTURE OF POST-MARKET SURVEILLANCE PROGRAMME

The design to be used in post marketing surveillance programme will depend on the objectives of the study, which must be clearly defined. Any specific concerns to be investigated should be identified and explicitly addressed by the proposed methods including sampling plan, sample collection and analysis.

The post market surveillance programme will be reviewed after every three years. However, the review may be necessitated by changes in applicable laws and regulations governing TMDA and when need arises. Suggestion for amendments, additions and improvements to the programme should be directed to the Director General.

Post marketing surveillance Programme shall contain the following details:

- a) Introduction
- b) Definition of terms (if any)
- c) Situation analysis (SWOC analysis)
- d) Risk Management
- e) Criteria used for selection of the products to be monitored

- f) Objectives of the PMS Programme
 - i. Broad Objective
 - ii. Specific Objective
- g) Methodology
- h) Enforcement
- i) Organization, Management and responsibility of the personnel involved in the implementation of PMS programme
- j) Resource needed
- k) Training
- l) Monitoring and evaluation
- m) Results and Dissemination
- n) Annexes

3.1 Introduction

Provide any background information on the issue of quality, safety and effectiveness of medicinal products and justification of conducting PMS for the specific products

3.2 Definition of terms

Provide meaning of terms used in the document (If any)

3.3 Situation analysis (SWOC analysis)

This is a systematic collection and evaluation of organization internal and external environment that may influence organization performance and choice of strategies. During the documentation of situation analysis, TMDA should consider the following:-

- a) Needs of PMS programme
- b) Current and future strengths, weaknesses, opportunities and constrains.

3.4 Risk Assessment

Risk Assessment is an effective means of identifying process risks and determining the most cost effective means to reduce those risks. Risks must be identified correctly before TMDA can develop PMS Programme.

TMDA should use both quantitative risk assessment and qualitative risk assessment tools and methods depending on availability of data, and information systems to support the assessments.

3.5 Criteria for Selection of Medicines

In preparing PMS programme the selection of medicines is among the critical factors. The criteria for selection of products to be surveyed should be considered as explained in section 2.5.1 of these guidelines.

3.6 Objectives of the PMS Programme

Explain the broad objective and specific objectives of the proposed PMS Programme.

3.7 Methodology

This section explains what activities to be done in implementing PMS programme. These may be includes preparation of sampling plan, selection of sampling areas, training of staff involved in activities, sampling screening, laboratory testing, evaluation of results and report preparation. Refer section 2.5 of these guidelines.

3.8 Enforcement

This section explains the necessary legal actions which will be instituted in order to protect public from further harm and to improve quality of the products on the market. Refer *section 2.8* of these guidelines.

3.9 Organization, Management and responsibilities

The implementation of PMS should involve all necessary stakeholders inside and outside the Authority. This section explains how the programme will be organized, managed and what are the key responsibilities of each stakeholder participating in the programme. Refer to section 2.10 of this guideline.

3.10 Resource needed

This section mention all resources needed in implementing PMS programme. Detailed Budget of PMS activities should be prepared and attached.

3.11 Monitoring and evaluation

This section explains how the implementation of PMS programme should be monitored and evaluated. Refer *section 2.9* of this guideline.

3.11.1 Results and Dissemination

PMS report should be made available to the public through different ways of communication. This section explains how the information will be communicated to the public and all other stakeholders..

3.11.2 Forms

The following are the key documents which should be attached in the proposed PMS programme but not limited to:

- a) Timeline of the Programme
- b) Sampling plan
- c) Sample collection form (TMDA/DMC/CTP/F/002)
- d) Product information review and screening form (TMDA/DMC/CTP/F/003)
- e) Test request Form (F01/TMDA/DLS/SOP/002)
- f) PMS Process Flow Chart (TMDA/DMC/CTP/PF/005)
- g) Budget of PMS programme
- h) PMS reporting format