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MINISTRY OF HEALTH

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

GUIDELINES ON GOOD REVIEW PRACTICES FOR REGULATION OF MEDICAL DEVICES

(Made under section 52 (1) of the Tanzania Medicines and Medical Devices Authority Regulation.

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TMDA Headquarters, Plot No. 56/1, Block E, Kisasa B Centre, Hombolo Road, P. O. Box 1253, Dodoma - Tanzania,
Tel: +255 (26) 2961989/2061990/ +255(22)2450512/2450751/2452108,
Email: info@tmda.go.tz, Website: www.tmda.go.tz, Toll free: 08001100834

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ABBREVIATIONS AND ACRONYMS

GMP	-	Good Manufacturing Practices
GRevP	-	Good Review Practices
MAB	-	Ministerial Advisory Board
MAH	-	Marketing Authorization Holder
MDA	-	Medical Devices Registration
MoH	-	Ministry of Health
NMRAs	-	National Medicines Regulatory Authority
NRA	-	National Regulatory Authority
QM	-	Quality Management
QMS	-	Quality Management System
QRM	-	Quality Risk Management
SOP	-	Standard Operating Procedure
TMDA	-	Tanzania Medicines and Medical Devices Authority
WHO	-	World Health Organization

ACKNOWLEDGEMENTS

The first edition of the guidelines intend to provide guidance on the principles and processes of good review practice (GRevP) for use in regulation of medical devices and in vitro diagnostic devices within TMDA. It's my hope that the information contained in these guidelines will help to achieve successful review outcomes.

I wish to take this opportunity to thank all who in one way or another assisted in the review of this guidance document.

I would like to sincerely thank TMDA staff for their tireless efforts in developing these Guidelines. Special thanks are extended to Ms. Rehema Mariki, Ms. Gudula Mpanda, Dr. Shani Maboko, Ms. Neema Nagu, Dr. Athanas Mseki, Mr. Edinanth Gareba, Mr. Kazmil Kishosha, Ms. Emmanuela Mkalawa and Ms. Edina Zebedayo.

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Kissa. W. Mwamwitwa
Director of Medical Devices and Diagnostics Control

FOREWORD

TMDA is increasingly seeking ways to improve performance and ensure the quality of its regulatory system. GRevPs are an integral part of overall good regulatory practices and focus on medical devices review aspect of regulatory work.

Review is a highly complex, multidisciplinary assessment of the medical devices application to ensure that they meet the scientific and evidentiary standards for quality, safety and performance. It forms the scientific foundation for regulatory decisions.

To facilitate this, the first edition of the Guidelines on Good Review Practices has been developed. The document describes the internal processes conducted during regulation of medical devices and provides recommendations to stakeholders on good review management principles and practices for the review of medical devices.

Good review practices ensures that review is managed in a consistent and efficient manner, thereby minimizing the number of assessment cycles necessary for approval and enhancing public's timely access to medical devices.

In general, this guidance document does not establish legally enforceable responsibilities. Instead the guidance prescribes the Authority's current thinking on the topic and should be viewed only as recommendations, unless specific regulatory statutory requirements are cited. Albeit, these guidelines do not legally bind TMDA, appropriate justification and supervisory concurrence are always placed before departure from the outlined procedures.

This document is envisioned as one building block in a set of tools and is sufficiently expandable to accommodate additional annexes or ancillary documents in the future. GRevP guidelines will from time to time be updated as responses to changing regulatory environments, feedback from stakeholders accrue ongoing efforts which will further be staged to improve and standardize internal processes across medical devices regulation, including quality systems implementation as well as innovations.



Dr. Adam M. Fimbo

DIRECTOR GENERAL

DEFINITION OF TERMS

The definitions given below apply to the terms used in this document. They may have different meanings in other contexts.

"**Act**" means the Tanzania Medicines and Medical Devices Act, Cap 219;

"Authority" means the Tanzania Medicines and Medical Devices, or the acronym "TMDA" established by Section 4 of the Act;

"Applicant" means a person or company who submits an application for marketing authorization of a new medical device, an update to an existing marketing authorization or a variation to an existing marketing authorization;

"Application" means the information provided by the applicant to the Authority for evidence-based assessment and marketing authorization decision;

"Assessor" means any qualified personnel who participate in the technical aspects of medical devices assessment and registration process;

"Assessment" means highly complex, multidisciplinary assessment of medical devices applications to determine whether they meet scientific and evidentiary standards for quality, safety and performance. It forms the scientific foundation for regulatory decisions;

"Assessment procedure" means the approach or plan of action that an assessor uses to process and evaluate a medical product application;

"External assessor" means assessor outsourced from outside TMDA;

"Good review practices (GRevP)" means documented best practices for any aspect related to the process, format, content and management of a medicinal product assessment and registration process;

"Medical Devices Vigilance" refers to science and activities relating to the detection, assessment, understanding and prevention of adverse events/incidents or any other possible device-related problem.

"Marketing authorization" means approval to market a medical device in Tanzania. It is a legal document issued by the Authority that permits the marketing or free distribution of a medical device in Tanzania after assessment of quality, safety, and performance. In terms of quality, it establishes inter alia the detailed composition and formulation of the product and the quality requirements for the product and its ingredients. It also includes details of the packaging, labeling, storage conditions, shelf-life and approved conditions of use;

"Post Marketing Surveillance (PMS)" refers to systems for monitoring quality, safety and performance of medical devices and diagnostics after they have been registered or notified and released on the market. It is the mechanism in place to assess the medical devices used by the public in a wide range of environment over an extended period;

"Principles (of a good review)" means the important GRevP elements to implement to achieve successful assessment and registration outcomes;

"**Project management (for the assessment and registration process)"** means the planning organization and resources to achieve a complete and high-quality review of an application within a specified time frame;

"Quality management (QM)" means the coordinated activities that direct and control an organization with regard to quality;

"Quality management system (QMS)" means an appropriate infrastructure, encompassing the organizational structure, procedures, processes and resources and systematic actions necessary to ensure adequate confidence that a product or service will satisfy given requirements for quality;

"Regulatory convergence" means the process whereby regulatory requirements, approaches and systems become more similar or aligned over time as a result of the adoption of internationally recognized technical guidance, standards and best practices;

"Standard operating procedure (SOP)" means an authorized written procedure giving instructions for performing operations (both general and specific);

"Transparency" means defining policies and procedures in writing and publishing the written documentation, and giving reasons for decisions to the public;

1. INTRODUCTION

Tanzania Medicines and Medical Devices Authority (TMDA) is an Executive Agency under the Ministry of Health (MoH) responsible for regulating the quality, safety and effectiveness of medicines, medical devices, diagnostics, biocidal and tobacco products. The functions of TMDA are provided for in the Tanzania Medicines and Medical Devices Act, Cap. 219.

TMDA has consistently documented good review practice (GRevP) through standard operating procedures (SOPs), assessment templates and other guidance documents. However, developing and documenting GRevP as a single set of guidance may address problems with;

a) The medical devices and in-vitro diagnostics assessment regulatory processes,
b) Enhance assessment practices of applications for marketing authorization,

quality audit and premises licensing, importation and exportation of medical devices and in-vitro diagnostics,
c) Enhance assessment practices of reported adverse events/incidents, and
d) Provide clarity to applicants on our internal procedures.

The guidelines highlight the following areas: –

a) Implementation of good review practices;
b) The structural arrangement of medical devices and in-vitro diagnostics assessment and registration;
c) Management of the assessment process;
d) Critical thinking during dossier assessment; and
e) Communications.

1.1 Objective of this document

The objective of this document is to provide guidance on the principles and processes of GRevP for regulating medical devices and diagnostics assessment within TMDA. These guidelines do not cover detailed procedures on how assessment is conducted, therefore they should be read in conjunction with the existing documents related to regulation of medical devices and diagnostics.

1.2 Scope

This document applies to the assessment review of quality, safety and performance of medical devices and diagnostics in the country. It also provides guidance on regulations of Medical Devices in the country. The concepts will be applied to the entire product life cycle from investigational testing to new product applications, variations to existing marketing authorizations, post marketing surveillance and maintenance of registration of the product within the TMDA register.

2. IMPLEMENTATION OF GOOD REVIEW PRACTICES

2.1 Main objective of GRevP

The main objective of GRevP is to help achieve timeliness, predictability, consistency, transparency, clarity, efficiency and high quality in both the content and management of assessment regulatory processes. This is done through the development of assessment tools and learning activities.

The Authority has implemented various assessment tools including, guidelines for different regulatory procedures, assessment guidance and templates, standard operating procedures, monitoring and assessment systems.

2.2 Core Values

GRevP are developed based on the Authority's core values of Transparency, Accountability, Quality, Creativity, Team work, Integrity and Customer focus. Therefore, the assessment review processes are all governed by these attributes. These core values assessments are summarized the table below.

Core value	Implementation
Teamwork	Evaluation and registration of medicines is supported by various Sections including Communications and Public Education (CPE), ICT, Inspectorate and Laboratory Services. This fosters a cooperative approach to ensuring that the public gets access to quality, safe and efficacious medicines.
Integrity	Personnel involved in medicines registration and evaluation are held to the highest standards of conduct and commitment while acting in the best interest of the country.
Customer focus	GRevPs guides evaluators to ensure that the customers' needs and expectations are at the forefront of our work
Transparency	Stakeholders have access to Authorities publications (Act, regulations, and guidelines) for technical assistance with regards to the evaluation and registration of medicines. Communications are made timely govern by Client Service Charter and all regulations decision reasons are communicated to the applicants.
Accountability	The Authority's roles, requirements and responsibilities for evaluation and registration of medicines are outlined in Regulations making the Authority accountable for timely accessibility of quality, safe and efficacious medicines
Quality	Quality control procedures are implemented throughout the marketing authorization process. These procedures are governed by GRevP that enables consistency and

	efficiency hence ensuring the utmost quality of evaluation and the resultant regulatory action
Creativity	Creativity is embraced during service delivery to ensure that TMDA customers get optimal services in a timely and convenient manner

2.3 Principles of a good review

The principles of a good review describe the GRevP elements that are important to implement in order to achieve successful assessment outcomes in line with the objectives of GRevP. The Authority has adopted 10 key principles of a good review to serve as a solid GRevP foundation upon which the Authority will continue to build. The principles are as follows:

a) Balanced

A good review is objective and unbiased.

b) Considers context

A good review considers the data and the conclusions of the applicant in the context of the proposed conditions of use and storage, and may include perspectives from patients, health- care professionals and other regulatory authorities analyses and decisions.

c) Evidence-based

A good review is evidence-based and reflects both the scientific and regulatory state of the art. It integrates legislative, regulatory and policy frameworks with emerging science.

d) Identifies signals

A good review comprehensively highlights potential areas of concern identified by the applicant and the reviewers.

e) Investigates and solves problems

A good review provides both the applicant's and the reviewers' in-depth analyses and findings of key scientific data and uses problem-solving, regulatory flexibility, risk-based analyses and synthesis skills to devise and recommend solutions and alternatives where needed.

f) Makes linkages

A good review provides integrated analysis across all aspects of the application:

Pre clinical; non clinical; clinical; chemistry/bio compatibility; manufacturing; and risk management plan. It includes timely communication and consultation with applicants, internal stakeholders and, as needed, with external stakeholders who have expertise relevant to the various aspects of the application.

g) Thorough

A good review reflects adequate follow-through of all the issues by the reviewers.

h) Utilizes critical analyses

A good review assesses the scientific integrity, relevance and completeness of the data and proposed labeling, as well as the interpretation thereof, presented in the application.

i) Well-documented

A good review provides a well-written and thorough report of the evidence-based findings and conclusion provided by the applicant in the dossier, and the reviewers' assessment of the conclusions and rationale for reaching a decision. It contains clear, succinct recommendations that can stand up to scrutiny by all the parties involved and could be leveraged by others.

j) Well-managed

A good review applies project and quality management processes, including clearly defined steps with specific activities and targets.

3. REGULATION OF MEDICAL DEVICES AND DIAGNOSTICS

The Directorate of Medical Devices and Diagnostics (DMD) is responsible for actively managing assessment of all medical devices regulatory processes. This is implemented through three sections namely;

a) Medical Devices Assessment Section (MDA)
b) Premise Licensing and Compliance Section (MDL)
c) Vigilance and Post Marketing Surveillance Section (MDV)

Each section is headed by a manager who is accountable for ensuring good review practices are in place and implemented throughout the regulatory processes. This maximizes both the potential for a positive public health impact and the effective and efficient use of resources. Effectiveness of the processes is dependent on multiple factors, principles and systems as described below.

3.1 Monitoring and assessment (Project Management)

Planning, monitoring, and assessment of regulatory activities are performed by all staff of the section led by the respective managers, This, coupled with timely informative communications and clearly defined work instructions ensures that timelines are met.

Principles of project management are implemented during processing and review for planning, organizing and resource allocation. This aids achievement of complete and high-quality assessment of applications within a specified time frame. All applications are made electronically through an online application portal which allows complete electronic management of each stage of assessment.

Monitoring of applications is achieved using an electronic technique. This electronic system has evolved with changes in technologies, techniques, regulatory practices, TMDA resources and workload. It is expected that continuous use of the system will necessitate further advancements, however at all times the system shall enable:

a) Receiving, screening, invoicing and storage of applications;
b) Assigning and distribution of applications for assessment;
c) Communicate with applicants on matters relating to their specific applications
d) Interpretation of the data to show the progress of one application as well as that of many applications under assessment at any one time;
e) Interpretation of the data to help in decision-making with respect to balancing workload against resources; and
f) Monitoring that can be performed and/or interpreted by the Authority.

3.2 Quality Management

Quality Management System (QMS) is an integral part of the DMD procedures. The QMS principles include standardized procedures to ensure that GRevP are in place, regularly monitored and subject to continuous improvement. In addition to standardizing processes and procedures to provide consistency and predictability, QM

plays a significant role in robust regulatory decisions and actions.

Implementing QM is an interactive cyclic process that incorporates lessons learned with regard to improved processes and decision-making. All personnel involved in assessment the medical devices and diagnostics review processes are responsible for the continual implementation of quality management principles.

The quality cycle implemented by the Authority consists of four key components: -

1. say what we do
2. do what we say
3. prove it
4. improve it.

This cycle ensures that GRevPs are not just esoteric guidelines (say what we do) but become embedded in the daily practice of the Authority (do what we say). Quality management is also in place to review the Authority's practice (prove it) and evolve where necessary, either in response to evolving regulatory science or through the adoption of a new review process and procedures (improve it). A description of the key components of QMS is presented in table 1 below.

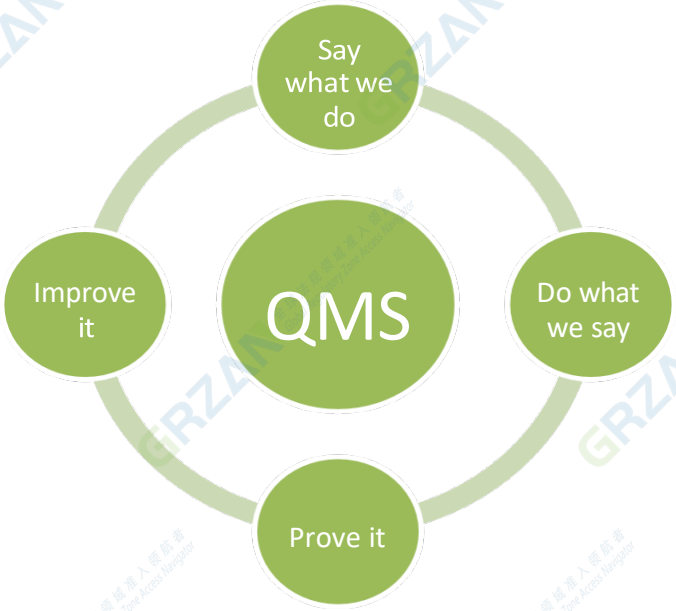


Figure 1: Cyclic representation of the key components of Quality Management Systems

Table 1: Key components of the Quality Management Cycle

QMS component	Interpretation
Say what we do	Availability of key documents, such as SOPs assessment guidance and templates. Defined processes for decision-making, such as decision frameworks, time frames for completion and communication of reviews, use of external assessors, public meetings and peer-review.
Do what we say	Record and collect key documents, such as minutes of meetings and teleconferences, memoranda, letters and reports.
Prove it	Ensure that review procedures and templates are being consistently interpreted and applied through the assessment of various inputs, such as internal and external feedback and periodic assessment of practices. Assess public health impacts of regulatory decisions, such as through a lessons-learned session that could include assessing the impact on disease, the health-care system and any unintended consequences.
Improve it	Review documentation and decision-making processes regularly. Introducing improvements to the review and decision-making process specifically in internal assessment of a review; peer review; internal quality audits; self-assessments; analyses of feedback from stakeholders; post-approval analysis of the decision in collaboration with other authorities; the public and applicants; and analysis of impact on public health. Implement new and improved work practices, the latest assessment techniques, and scientific and technological advancements.

3.2.1 Standard Operating Procedures (SOPs)

Handling of each activity is guided by specific SOPs which: -

a) Outline the workflow processes that facilitate project management when there are multiple activities to perform;
b) Enables handling and reviewing processes in a consistent manner; and
c) Facilitate staff training.

The DMD has developed SOPs for managing all review processes from receiving and handling applications, reports and samples, distribution and assigning documents as well as for technical assessment and communicating to applicants. The SOPs are used in conjuncture with additional tools and guidance to support effective implementation of the tasks. Such tools include assessment guidance tools, templates; forms, registers and checklists to provide detailed instructions on conducting a particular procedure and give advice on handling different situations in the course of performing the procedures.

In addition, the Authority has developed training program and procedures to ensure

consistent training of all regulatory experts involved in medical devices and diagnostics review. Furthermore, procedures for administratively handling applications after final recommendations are also implemented. These include the process of convening technical committees and where necessary publishing information on approved or rejected medical devices and diagnostics.
To promote continuous improvement, all SOPs and accompanying templates, registers, checklists and forms are reviewed every three (3) years. Nevertheless, all these documents may be reviewed any time when technological advances occur or scientific and regulatory thinking evolves. This evolution could be related to influences including scientific progress, international harmonization of guidelines, changes in review strategy, available resources, and increased volume of applications, collaborative work-sharing and national laws and regulations, among others

While these SOPs, assessment guidance, templates, registers and checklists are internal documents, guidelines are made available to provide stepwise instructions to applicants on how to fulfill regulatory requirements.

4. MANAGING THE ASSESSMENT PROCESSES

4.1 Roles and responsibilities

4.1.1 Applicant

Applicants are expected to be conversant in international regulatory requirements as well as TMDA specific requirements. It is the responsibility of the applicant to:-

a) Provide authentic and complete scientific documents to support their applications;
b) Ensure that all submissions (of additional data) are submitted within the deadlines; In case of marketing authorization,
   i. Ensure that their product meets all requirements to be retained in the register of registered medical devices and in-vitro diagnostics;
   ii. Submit any variations to the Authority in line with the requirements stated in the variation guidelines;
   iii. Renew their registration every five (5) years; and
   iv. Conduct market surveillance activities once the product has been granted marketing authorization.
   v. Monitoring the device on the market and inform the Authority immediately after the detection of any problem relating to a registered device such as serious manufacturing defects which may endanger public health
   vi. Handling device recalls.
   vii. Providing technical support and services to users of registered device (s).

NB; If the applicant is not resident in Tanzania, then he shall appoint a Local Responsible Person (LRP).

4.1.2 Authority

Ultimately, the responsibility of the Authority is to ensure the quality, safety and performance of medical devices and in-vitro diagnostics by allocating sufficient and competent human resource to implement GRevP. To achieve this, regulatory experts are expected to become thoroughly familiar with pertinent GRevP and to adhere to these GRevP during assessment review unless a particular part of a GRevP is not applicable to a particular review or the reviewers receive supervisory instruction to do so otherwise. Any deviation from the GRevP should be adequately documented and justified.

All Managers within DMD are responsible for: -

a) Ensuring that tools to execute GRevP are developed, implemented, updated and followed
b) Communicating specific instructions to deviate from the GRevP when appropriate;
c) Conducting training needs assessment and planning appropriate in-house training;
d) Overseeing the mentoring of regulatory experts; and
e) Advising Management on content and policy within GRevP and appropriate training courses

4.2 Types of Review processes

a) Marketing Authorization
b) Quality Audit Desk Review
c) Importation and Exportation Processes
d) Post Marketing Surveillance and Vigilance

5. MARKETING AUTHORIZATION (MA)

MA involves scientific review of evidence documents to ensure quality, safety and performance.

The Authority has developed guidelines for MA of MDR which classifies MDR into four classes based on their risk namely; A, B, C and D with class A being devices with low risks and class D high risk. The type and extent of assessment conducted depends on the risk of the device.

5.1 Types of Marketing Authorization

The Authority has established two main routes for MA of medical devices and in-vitro diagnostic devices as follows:

i. **Notification:** this procedure is applied for select low risk, class devices i.e. laboratory equipment and devices that are non-sterile, non-active and do not have measuring functions as applied in the regulation and guidelines for notification of medical devices exempted from registration.

ii. **Registration:** this procedure is applied for class A devices that are active, sterile and with measuring functions also devices that fall under classes B, C and D as applied in the regulation and guidelines.

5.2 Stages of assessment

5.2.1 Pre-checking of applications

There are separate assessment procedures and templates for new applications, re-registration applications, query responses and variation applications.

Assessment of medical devices and in-vitro diagnostics start with pre-checking of applications to confirm the completeness of the application in order to facilitate the subsequent scientific review. This comprises checking the application to ensure that it is well-organized, correctly classified and complete. Identifying missing documents in the application prior to scientific review enables the Authority to avoid spending time and review resources on an application that does not allow regulatory decision- making.

It is essential that applicants are aware of the Authority's expectations at both stages, including the target time frames, guidelines, requirements, templates and checklists. This results in a more predictable and clear process for applicants. In turn both parties' benefit when complete documents are submitted at the outset.

5.2.2 Dossier assessment

The second stage is dossier assessment where a scientific review is undertaken. This stage has two critical steps; first assessment and second assessment of the assessed

report. This means that; each application is assessed by two assessors based on first-in first-out concept while taking into consideration the competency, expertise and experience of the assessor. These stages are put in place as a safeguard to ensure quality of the report and that no critical issue is overlooked.

The need for site inspection (Quality audit) to verify the compliance of manufacturing sites is considered during the registration procedure. Additional communication with the laboratory is conducted when the need for sample analysis arises.

This stage is complete once communications have been finalized and sent to applicants. The dossier assessment stage is usually the longest as it may require multiple rounds of communications to ensure that the data provided satisfies the regulatory requirements.

5.3 Legal and Administrative Procedures

Once the assessment has been completed and final recommendations reached, the legal and administrative procedures begin. At this stage, notification applications are submitted for DMD approval, Class A and B applications are submitted for DG approval while Class C and D applications are presented before the technical committee for registration consideration.

6. QUALITY AUDIT

Quality audit targets to assess the compliance of MDR and IVD manufacturing facilities to minimum requirements of the latest version of ISO 13485 standards and other relevant standards applicable to a specific device.

Compliance verification of manufacturing facility is done through physical inspection of manufacturing facility or desk review. Quality Audit applications are received through RIMS. The submitted application is processed as follows.

6.1 Pre-Checking

This involves checking of completeness of the submitted documents which includes filled application form, Site Master File (SMF) and Quality Manual.

6.2 Pre-assessment

At this stage, the submitted application is reviewed to categorize the applied facility into those qualifying for desk review and physical quality audit.

6.3 Assessment

Applications qualifying for desk review are channeled for assessment. This stage has two critical steps; first assessment and second assessment. This means each application is assessed by two assessors assigned based on a first-in first-out concept while taking into consideration the competency, expertise, and experience of the assessor. These stages are put in place as a safeguard to ensure that no critical issue is overlooked and that GRevP are followed.

The final recommendations from regulatory experts are communicated to DMD through MMDL if satisfied, shall submit to Director General for final approval. Upon DG's approval the certificate (s) of compliance is generated through RIMS and sent to the applicant.

7. IMPORT AND EXPORT REVIEW

There are two types of import and export applications i.e. normal and special case applications whose requirements are described in the Guidelines for Importation and Exportation of Medical Devices Including In-vitro Diagnostics and Laboratory Equipment.

Processing of normal case importation applications focuses on verification of the authenticity of the uploaded documents without conducting scientific review. However, due to the sensitivity or criticality of special importation permits, the special case applications are subjected to review prior to issuance.

7.1 Review and processing application

The first stage involves technical assessment of the application to confirm whether the minimum requirements of quality, safety and performance have been met for products under application. This includes review of all documents submitted to support importation of unregistered devices. The second stage is manager review where the Manager reviews the assessment recommendations.

7.2 Legal and Administrative Procedure

The final recommendations from regulatory experts are communicated to DMD through MMDL for final approval. If the application meets the prescribed requirements, the applicant will be required to pay import fees as stipulated in the Fees and Charges Regulations in force, and the Authority will issue an import permit thereafter payment.

8. ADVERSE EVENTS/INCIDENTS

The Authority ensures the devices safety, quality and performance through monitoring of possible occurrence of adverse events/incidents. Reporting Adverse Events/Incidents (AE/AI) aids regulatory decision making regarding medical devices. AE/AI reporting mechanisms are described in the Guidelines for Vigilance System in Tanzania.

Review of medical devices adverse events/incidents starts with acknowledgement feedback for receipt of the report to the reporter and followed by causality assessment of the report. The findings of the assessment determine the regulatory action to be taken.

8.1 Causality assessment

Assessment has two critical steps; first assessment and second assessment of the report. This means that each application is assessed by two assessors assigned based on either severity of the incident and first-in first out concept-based expertise and experience of the assessor. These stages are put in place as a safeguard to ensure that no critical issue is overlooked and that GRevP are followed. This stage is complete once regulatory actions are reached and communications have been made to either the reporter or manufacturer of the reported device.

8.2 Regulatory decision and feedback

Depending on the outcome of the assessment of ADE/AI the Authority may request change of information of a registered device, suspend, withdrawal, revoke marketing authorization, request of additional data or issue public notice alert. These Regulatory decisions are communicated to all stakeholders including the reporter of the ADE/AI.

9. REGULATORY EXPERTS

The quality, timeliness and success of review processes are dependent on adequate human resources who may be internal (within TMDA) or external. The Authority may source experts from different academic disciplines including but not limited to Pharmacy, Medicine, Biomedical Engineering, Medical Laboratory Sciences and Biotechnology.

All experts employed by the Authority are bound to Codes of Ethics and Conduct for Public Services and sign the declaration of conflicts of interest every calendar year as part of the requirements of the Public Service Regulations. The expert's capacity relates to many factors including scientific knowledge and skills, regulatory knowledge and experience. These form the core competencies for personnel involved in the various aspects of managing and conducting review.

Effective training is a requirement for maintaining core competencies thus, the Authority has developed training program and procedures to provide consistent quality of training for all experts. Moreover, training needs assessment is done on an annual basis to determine knowledge gaps for individual experts as well as knowledge gaps of the whole Directorate.

9.1 External Experts

Pursuant to Section 5 (1) (e) of the Tanzania and Medical Devices Act, Cap 219, the Authority may select external experts following rigorous screening of qualifications of different professionals to ensure the integrity of reviews and recommendations. Only qualified personnel that are free of actual or perceived conflicts of interest are listed as external experts.
To be free of any conflict of interest means that the assessment decision or recommendation is not likely to be influenced by personal, family, financial or professional motives, including those of employers when an external expert is also a consultant to a regulated party. All external experts sign confidentiality agreements and declarations of conflict of interest at the beginning of their tenure.

During the performance of any TMDA activity, the external experts are mandated to adhere to TMDA's code of conduct for external experts; failure to comply with the code of conduct may lead to the de-listing of the external experts before the end of his/her tenure. The TMDA External Experts include members of the Medical Devices and Diagnostics Regulation Technical Committee, External Assessors, and Individual Consultants.

The tenure for external assessors is one financial year which can be renewed indefinitely based on the individual performance while for Technical Committee Members is three years in accordance to respective terms of reference. The performance of external assessors is monitored annually through performance appraisal which is conducted at the end of each year to determine the overall quality of assessments done by the individual assessor. This process guarantees that each external assessor upholds our core values and consistently provides quality output. Following this appraisal, the list of external assessors is updated. If an assessor's appraisal deems that his/her work is

unsatisfactory, he/she shall be delisted.

9.2 Technical Committee Members

DMD has one (1) technical committee, namely Medical Devices and Diagnostics Regulation Technical Committee. The TC members are appointed from outside the Authority by Director General upon consultation with the Director of Medical devices and Diagnostics (DMD). Their main role is to provide specialized advice on matters related to regulation of medical devices to the Director General in line with the Tanzania Medicines and Medical Devices Act, 2003, governing laws and regulations and relevant Guidelines. The tenure for Technical Committee Members is three years in accordance to respective Terms of Reference.

9.3 External assessors

The Authority issues public notice annually, inviting qualified external assessors to express interest in performing various regulatory activities related to regulatory control of medical devices and in-vitro diagnostics. The tenure for external assessors is one financial year which can be renewed indefinitely based on the individual performance. The performance is monitored annually through performance appraisal which is conducted at the end of each year to determine the overall quality of assessments done by the individual assessor. This process guarantees that each external assessor upholds the Authority's core values and consistently provides quality output. Following this appraisal, the list of external assessors is updated. If an assessor's appraisal deems that his/her work is unsatisfactory, he/she shall be delisted.

10. CRITICAL THINKING DURING REVIEW

Critical thinking requires an objective and systematic approach to analyzing information and to problem-solving. It relies on the collection of data and evidence-based decision-making instead of generalizing from one's own experience, intuition or trial and error. Decisions should be reproducible and clearly understood by others.

Nevertheless, every regulatory decision involves judgment. Therefore, core competence in public health and bioethics, and the ability to integrate up to-date scientific knowledge with an understanding of the evidentiary standards for regulatory action (including the flexibility inherent in those standards and regulations), also guide decisions.

Beyond their professional qualifications, regulatory experts critically appraise the information presented in an application and do not just accept it as presented. This skill is developed and strengthened during the training process and routine quality assurance.

The review focuses on important issues in the application, rather than on data that provide more information, but will not ultimately affect the outcome of the process i.e. need to know information versus good to know information. Nevertheless, good judgment is required to ensure a balanced decision. This includes, where applicable, using international harmonized regulatory requirements and adopting regulatory approaches that show flexibility to maximize public health benefits while minimizing adverse, unintended consequences.

Regulatory decision-making and recommendations are influenced by the following factors:-

a) The best available scientific evidence and state of knowledge;
b) The public health needs of the country; and
c) The state of health-care system.

Consideration of our health-care delivery system may necessitate changes in scheduling of a particular medical devices and in-vitro diagnostics or refusal of registration of a device that is known to meet quality, safety and performance standards because of the potential of misuse.

In decisions to grant marketing authorization the benefits must, on balance, outweigh the risks, based on sound scientific evidence. Within the assessment report, assessor provide the scientific rationale for decision making while considering the regulatory requirements. This provides a record to ensure integrity of the review processes. The assessment report is the decision-making document used by the Authority to make a final recommendation. Therefore, it addresses dissenting, evidence-based views and clearly identifies the information that was considered.

11. COMMUNICATIONS

Good communication is critical and has many advantages for the Authority, stakeholders and the general public. Clear and timely communication improves the efficiency of the review process, allowing faster access to important medical products.

The Authority actively communicates with its stakeholders through the official TMDA website. Specifically, any changes made or new requirements introduced are articulated to applicants via public announcements, updating on website or through emails. The aim of this communication is to provide insight into the Authority's current thinking and expectations hence, allowing applicants to provide better quality applications.
Moreover, new guidelines, regulations and regulatory requirements are shared with stakeholders for comments prior to implementation. This ensures that the requirements are mutually agreed upon and understood; thus, improving compliance. Open communication ultimately improves the efficacy of assessment process allowing patients faster access to medicines.

11.1 Intra-agency

Review is conducted in a collaborative environment requiring expertise from different sections within the TMDA. This collaboration is fostered throughout the device's life-cycle. Regulatory decisions are regularly communicated to other key players within the Authority for implementation.
Section 5 of the Act provides the main function upon which the Authority should execute. Among the functions is to collaborate and cooperate with other national and international organizations. That being the case, the Authority engages with other government institutions and International Organizations to obtain expert opinion and information sharing regarding regulated products. The Authority may also engage other NRAs on various regulatory-related issues to facilitate greater regulatory convergence.

11.2 With applicants

Communication with individual applicant on specific applications throughout the review process can be done through official letters, online application notifications, telephones and electronic mails, the latter being used for minor clarifications and requests. These communications aim at: -

a) Fostering efficient medical product development through the provision of scientific advice;
b) Increasing applicants' understanding of evolving regulatory expectations in a changing medical and scientific environment;
c) Increasing the Authority's understanding of challenges and trade-offs with various requirements;
d) Fostering applicants' compliance with requirements; and
e) Informing applicants about the progress and status of the review of their applications.

The Authority strongly encourages input from applicants, particularly feedback on guidelines development and implementation as it creates dialogue regarding regulatory

practices. The feedback enables the Authority to address any procedural or technical shortcoming and to improve services.

11.3 With external experts

The Authority engages external experts through telephone, electronic mail, and official letters. Expertise in the scientific assessment of the quality safety and efficacy of medical products is not limited to applicants and NRAs. When needed, the Authority may identify and outsource experts from different institutions inter alia Academia consulting companies, health institutions, health programs and, departments, pharmaceuticals, medical associations, and individual experts.

11.4 With the general public

The Authority communicates with the general public about its mission and accomplishments in order to foster greater public awareness, understanding and confidence in the Authority. For the TMDA, transparency initiatives usually involve web-based information about how it is organized and operates, its decision-making processes and criteria, and its actions, such as application approvals and product recalls. Additionally, there are mechanisms in place whereby the public can provide input on medical needs, efficacy expectations and risk tolerances, such as through public meetings and advisory committee. Providing the public with the opportunity to comment will permit enhanced content and feasibility of proposed guidelines and regulations.

The general public may also be consulted on specific applications under assessment by the Authority where public opinion is considered to be required. There are various mechanisms, by which this can be achieved, such as surveys, focus groups, public meetings, workshops and appointments to advisory boards.

12. LIST OF DOCUMENTS GOVERNING THE MEDICAL DEVICES AND DIAGNOSTICS REVIEW PROCESS

The lists of documents governing the medical review processes are available at: www.tmda.go.tz,

13. DOCUMENT REVISION HISTORY

Revision Number	Date	Author	Description of change	Section(s) Modified	Approvals
00	December, 2023	MDA, MDL and MDV	First edition	N/A	DMD

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