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THE UNITED REPUBLIC OF TANZANIA
MINISTRY OF HEALTH

TMDA

TANZANIA MEDICINES AND MEDICAL DEVICES AUTHORITY

COMPLIANCE AND ENFORCEMENT POLICY

SECOND EDITION

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Vision
To be the leading Regulatory Authority in ensuring safety, quality and effectiveness of medicines, medical devices, diagnostics and other health related products for all.

Mission
To protect and promote public health by ensuring quality, safety and effectiveness of medicines, medical devices, diagnostics and other health related products.

Philosophy
TMDA strives to offer quality regulatory services in the pursuit of protecting public health and environment by using competent and dedicated staff.

Core values:
T - Transparency
A - Accountability
Q - Quality
T - Team work
C - Customer focus
I - Integrity

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ABBREVIATIONS AND ACRONYMS

ADDOs	-	Accredited Drug Dispensing Outlets
GMP	-	Good Manufacturing Practices
MoH	-	Ministry of Health
NEMC	-	National Environment Management Council
PoEs	-	Ports of Entry
TMDA	-	Tanzania Medicines and Medical Devices Authority
TRA	-	Tanzania Revenue Authority
C/S	-	Contrary to Section
GSDP	-	Good Storage and Distribution Practice
Cap	-	Chapter

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DEFINITIONS OF TERMS

In the context of this policy, the following words or phrases are defined as follows:

Act
The Tanzania Medicines and Medical Devices Act, Cap 219;

Authority
The Tanzania Medicines and Medical Devices Authority or the acronym TMDA;

Compliance Monitoring
Actions planned to maintain regular surveillance in order to evaluate compliance with applicable requirements of the Tanzania Medicines and Medical devices Act Cap 219 (herein to be referred to as the Act) and its associated Regulations. This includes a wide variety of fact gathering and assessment activities such as inspections, market surveys and a product sampling program;

Compliance Verification
Actions taken to verify compliance in response to information regarding known or suspected non-compliance with the applicable requirements of the Act and its associated Regulations. This includes actions such as information gathering either off-site or via on-site visits;

Compliance
The state of conformity of a regulated party (including a corporation, institution, individual or other legal entity) or a product with a legal or regulatory requirement;

Recall
Means a firm's removal from further sale or use, of a distributed product that presents a risk to the health of patients or violates the Act;

Seizure
To officially take away from a vendor or importer, to assume custody of products consignment stocked in the premises or at the port of entry. The intention is to stop the products' distribution to the public. Usually done for product shown to be falsified or of substandard quality or associated with unexpected illness or death;

Detention
The act of holding in custody a consignment pending resolution of outstanding issues by TMDA;

Regulated party
Means a person or entity responsible for complying with TMDA Act;

Actions that may be taken to induce, encourage or compel compliance with the Act and its associated Regulations;

Inspection
On-site monitoring and assessment against the applicable requirements of the Act and its associated Regulations. Inspections are routinely conducted on a predetermined cycle or as required to assess compliance;

Inspector
Any person designated as an inspector for the purpose of the enforcement of the Act under section 105(1) (a) & (c);

Marketing authorization
A legal document issued or approved by the Authority, authorizing the sale of a regulated product based on the quality and safety requirements of the Act and its associated Regulations; and

Controlled drugs
Means any narcotic drug, psychotropic substance and precursor chemical provided under Schedule 1 of the Tanzania Medicines and Medical Devices (Scheduling of Medicines Regulations 2015).

FOREWORD

Tanzania Medicines and Medical Devices Authority (TMDA) is a semi-autonomous regulatory body under the Ministry of Health, which regulates amongst other things importation, exportation, manufacture, storage and distribution of medicines, medical devices and diagnostics. TMDA was established under section 4 of the Tanzania Medicines and Medical Devices Act, Cap 219 and its mission is to protect and promote public health by ensuring quality, safety and efficacy of regulated products.

To achieve its mission, TMDA performs a number of regulatory functions which are derived from strategic plan(s) and implemented vide annual or business plan(s) of which activities and targets are monitored and evaluated systematically using agreed Key Performance Indicators (KPI). Some of the key regulatory functions performed by TMDA include inspection of outlets, registration and marketing authorization, licensing of outlets, market surveillance and control and vigilance.

During execution of the above functions, TMDA enforces the Act and its regulations by taking appropriate measures which may include recommending regulatory actions, sanctions and penalties to the regulated parties. Based on the fact that, the proposed regulatory measures have to be discharged in a fair, consistent and impartial manner; TMDA has revised the existing (first edition) Compliance and Enforcement Policy to cope with the rapid changing regulatory environment which is characterized by complex supply chains, scientific innovation, advanced technologies, changing customer behaviors and increased demand for transparency regarding decision-making process following regulatory activities. Generally, this policy aims to assist stakeholders and the public using regulated services and TMDA officers performing regulatory functions to ensure that consistent and uniform enforcement actions are observed as per requirements of the Act, its regulations and corresponding guidelines.

Amongst other contents, the policy describes the role of TMDA in delivering compliance and enforcement functions including tasks for regulated products, the roles of regulated parties and the Authority's relationship with consumers and healthcare professionals in relation to products and activities it executes. This policy is a proof of the Authority's commitment to transparency and its esteemed customers involvement and contributions in ensuring compliance with the Act and its regulations for the purpose of protecting and promoting public health.

It is expected that this policy will foster working relationship between the regulated party and the Authority, foster voluntary compliance and enhance smooth

compliance to the requirements of the Act and allow enforcement actions to be taken in cases where voluntary compliance has not been achieved.

Adam M. Fimbo
DIRECTOR GENERAL

1. INTRODUCTION

Tanzania Medicines and Medical Devices Authority (TMDA) is a semi-autonomous national medicines and medical devices regulatory body under the Ministry of Health, which is responsible for protecting and promoting public health by ensuring safety, quality and effectiveness of medicines, medical devices and in-vitro diagnostics.

TMDA was established under section 4 of the Tanzania Medicines and Medical Devices Act, Cap 219 with its functions outlined under section 5(1) of the Act of which amongst include control of manufacturing, importation, distribution, promotion and advertisement, sell of medicines, medical devices and diagnostics to ensure that these products meet the quality and safety specifications.

To promote effective implementation of the Act and its Regulations, the responsibility for control of quality and safety of the regulated products is shared among healthcare professionals, industries, government, end users and other stakeholders. To discharge its responsibility in a fair, consistent and impartial manner, TMDA developed the Compliance and Enforcement Policy in 2006, revised first edition in 2016 and this second edition.

The Compliance and Enforcement Policy provides guiding regulatory principles including a set of prohibitions and penalties in relation to the premises and products regulated. It also brings together the compliance and enforcement functions of the Authority and regulated parties within one document.

Proper realization of the existing Compliance and Enforcement Policy has been faced by various challenges including current regulatory environment which is characterized by complex global supply chains, rapid scientific innovation, advanced technologies, changing consumer behaviors and increased demand for transparency regarding regulatory decision-making process. To overcome these challenges, it has been important to revise the existing policy and come up with an up-dated version which will resolve and meet the current and foreseen environment.

This second edition Compliance and Enforcement policy is structured into eight (8) major parts including policy statement, responsibilities of both the Authority and regulated party, compliance and enforcement activities, inspection and descriptions for appeals for any dispute by regulated party. Moreover, the document delineates the role of TMDA in delivering a national compliance and enforcement activities for all products under its mandate, the roles of regulated party and the Authority's relationship with end users in relation to products and regulatory actions.

This document provides TMDA staff and stakeholders, as well as the public, with guiding principles for fair, consistent, uniform application and enforcement of the Tanzania Medicines and Medical Devices Act, Cap 219 and its regulations.

It is therefore expected that, the use of this policy will help to improve compliance and conduction of enforcement measures in a fair, consistent and impartial manner henceforth effective implementation of the Tanzania Medicines and Medical Devices Act, Cap 219.

2. PURPOSE

As part of regulatory responsibilities, TMDA monitors compliance, undertakes enforcement activities and works towards preventing non-compliance. This policy describes national compliance and enforcement approach for premises and medical products regulated under the Tanzania Medicines and Medical Devices Act, Cap 219 and its regulations. The policy also describes the roles of regulated parties and the Authority's relationship with health care professionals, end user and general public in relation to products and activities it regulates.

3. SCOPE

This policy applies to all products regulated by the Authority as prescribed in the Tanzania Medicines and Medical devices Act, Cap 219.

The regulated products include;

i. Human medicines,
ii. Veterinary medicines,
iii. Herbal medicines,
iv. Medical devices and in-vitro diagnostics and
v. Complementary products.

The associated activities include;

i. Manufacturing,
ii. Packaging/labeling,
iii. Processing,
iv. Fabrication of medical devices,
v. Selling,
vi. Storing,
vii. Testing,
viii. Importing and exporting,
ix. Distributing,
x. Promoting or advertising,
xi. Recall and disposal.

4. POLICY DESCRIPTION

This policy promotes customers compliance to the Tanzania Medicines and Medical Devices Act, Cap 219, its regulations and guidelines for purpose of protecting and promote public health. The policy describes the guiding principles and approaches to which TMDA and other stakeholders will follow to ensure consistency in carrying out enforcement measures. The following principles govern the Authority and stakeholders in enforcing the Act and its regulations.

4.1 Transparency

Transparency fosters trust, commitment and accountability to both parties. The Authority makes information on compliance and enforcement activities available to the public for effective implementation of the Act through various ways. For example, TMDA publishes on the website, list of registered products and list of Good Manufacturing Practices (GMP) compliant facilities so that customers can make informed decision when buying or wishes to import regulated products. Moreover, by making policies and guidance documents public, information on decision making process is clear and understandable to everyone.

TMDA provides access to information regarding compliance and enforcement actions while respecting privacy rights, where appropriate. Regulated parties can expect to see an increase in the type and scope of compliance and enforcement decisions made to public. This approach is in line with the Government transparency commitment to make government decisions, data and information more accessible to the public and everyone.

4.2 Fairness, Consistency and Impartiality

The Act and regulations are applied in a fair, consistent and impartial manner. The Authority follows a predictable, uniform and national approach to enforcement in Tanzania for all TMDA's regulated products, irrespective of where or by whom these products are sold, advertised, fabricated, processed, packaged/labeled, imported, distributed, tested or stored.

While TMDA strives for consistency in decision-making, the situation and the circumstances applicable to a particular context may activate different compliance and enforcement responses to address issues of non-compliance and to hold a non-compliant party responsible. The Authority takes a non-discriminatory and unbiased approach to its activities.

4.3 Risk-based approach

The Authority's activities are guided by the Authority decision-making framework. Risk assessment and risk management are important components of this framework. Risk can manifest in a variety of ways, such as sale of a product which

is unregistered, product not conforming to quality and safety specifications. The Authority's activities are structured to achieve the greatest impact and efficiency in addressing the identified risks. When the regulated products does not comply with the Act and associated regulations, the Authority conduct risk assessment as per TMDA risk management framework to establish appropriate type of regulatory action.

The assessment takes into account the distinctiveness of the product or the system that may pose a health risk to the patients. The health risks assessment may be based on the following factors;

i. Safety and efficacy profile or risk classification on the regulated products

ii. The route of administration of the medicinal product

iii. Deviation from prescription requirements in the course of medication of the product

iv. Complexity of the regulated activity or operations conducted in relation to the regulated product

v. Number of people exposed to the regulated product with health risks

In determining the most appropriate type of regulatory measures, TMDA balances the interests of regulated party without compromising quality, safety and effectiveness of medicines, medical devices and diagnostics and the need to maintain public confidence in the overall integrity of the regulatory system including the public's perception of risk. For example, TMDA will take into consideration:

i. The behaviors of the regulated party conducting the activity, such as whether the regulated party acted with apathy or carelessness, indifference or premeditation
ii. The degree of co-operation and responsiveness offered by the regulated party,
iii. The compliance history of the regulated party,
iv. The probability of repeat compliance issues,
v. The likelihood of the enforcement measures being effective in bringing the party into compliance or in mitigating the health risk.
vi. The risk to health and safety, including the absence of a valid marketing Authorization;
vii. The need to maintain public confidence in the programs administered by TMDA and,
viii. TMDA priorities and available resources.

Depending on the issue, additional factors may be taken into consideration such as the need to allow the public to have continued access to essential medical products or other unique situation.

4.4 Evidence-Based Decision

TMDA's compliance and enforcement actions as well as decisions shall be based on the best available evidence, information and science. Evidence is assessed neutrally and is based on the risk management principles for identifying, assessing, and managing risks. Where relevant evidence is incomplete or questionable, a precautionary approach may be taken. As new information becomes available, the risk may change and require a different approach to compliance and enforcement.

4.5 Commitment to Quality Services

TMDA is committed to provide quality services in response to customer needs and expectations. In performing its regulatory actions, TMDA balances the interests of regulated party without compromising quality, safety and effectiveness of medicines, medical devices and diagnostics by managing the Authority with utmost professionalism.

The Authority's commitment to quality services is demonstrated through the integration and promotion of quality management principles within the organization. The Authority quality objective is uniformity in fulfilling our compliance and enforcement responsibilities.

4.6 Qualified and Competent Staff

The Authority strives to offer quality regulatory services in the pursuit of protecting public health and environment by using qualified and competent staff. In such manner, TMDA staff receives regular training to ensure they are knowledgeable of the products, activities being regulated and the environment in which they are to apply such knowledge.

5. RESPONSIBILITIES

5.1 Roles and Responsibilities of TMDA

It is the Authority's responsibility to conduct enforcement activities in accordance with this policy. The Authority conducts inspections and other enforcement activities as per Act, regulations and guidance documents. Workforce involved includes trained inspectors and laboratory analysts. According to the Act, TMDA is empowered to appoint and authorize inspectors to conduct enforcement activities

to the regulated party. The powers of inspectors are described under section 106(1) (a)-(g) of the Act.

The Act also contains provisions for TMDA to seize, forfeit, condemn and destruct unfit regulated products in certain circumstances of non-compliances. Legal proceedings for offenses against the Act may be initiated by the Authority.

TMDA provides support to regulated parties, consumers and other stakeholders to become aware of their responsibilities with respect to the legislation governing medical products regulation in Tanzania, including the consequences associated with non-compliance. The support can be provided through television and radio programs, outreach programs, publications, news bulletin and fliers.

The maintenance and enhancement of quality and safety is a responsibility that is shared among government organs, manufacturers and dealers, end users, healthcare professionals and their respective associations.

5.2 Roles and responsibilities of other parties

It is illegal to sale, manufacture, import or distribute and promote human medicines, veterinary medicines, herbal medicines and medical devices in Tanzania without authorization of the Authority. Any person involved in an activity regulated under the Act has exclusive responsibilities for the safety, efficacy and quality of medical products.

5.2.1 Authorized and Regulated parties

Authorized and regulated parties that conduct business related to human medicines, veterinary medicines, herbal medicines and medical devices have the primary responsibility for the safety of any product they sell, manufacture, import or distribute to the public. These parties must comply with all legal and regulatory requirements.

The primary responsibility of a regulated party is to understand their obligations under the Act and to comply with these requirements. Regulated parties who fail to comply will be subjected to compliance and enforcement actions.

Any party conducting a regulated activity can be inspected by TMDA. Overseas manufacturers that conduct regulated activities in Tanzania or in relation to a product sold, imported or advertised in Tanzania are also subject to the requirement of the Act.

During an inspection, a regulated party is required to provide all reasonable cooperation and information necessary for the inspector to perform their duties. An inspector may request a regulated party to provide evidence that its facility,

equipment and procedures meet the applicable requirements. Obstructing or hindering an inspector who is carrying out their duties or functions is an offence under the Act. Regulated parties are therefore expected to:

i. Understand the relevant laws, regulations, guidelines and their obligations,
ii. Ensure their products, activities and processes comply with the applicable laws,
iii. Cooperate with inspectors during an inspection as required by law,
iv. Provide any document that may be requested by inspectors in line with the powers prescribed under section 106 of the Act.

5.2.2 Other regulated parties

Other parties may also be bound to provisions of the Act although they may not require an authorization from TMDA to perform certain activities. For example, retailers and wholesalers of human medicines, veterinary medicines retailers and health facilities do not require premises registration and business license from TMDA to operate their premises. Instead, they should obtain such certificates and licenses from the respective professional bodies such as the Pharmacy Council of Tanzania in case of operating business of retail and wholesale of human medicines, and the Veterinary Council of Tanzania in case of business of retail veterinary medicines.

End users have a responsibility for the maintenance of their health and the safe use of marketed and regulated products. They have the responsibility to use the products according to the manufacturer's instructions. In addition, end users are required to inform the TMDA of any problems that they encounter (hazards, adverse reactions, adverse events/incidents, malfunctions, and non-compliance) following the use of human medicines, veterinary medicines, herbal medicines and medical devices.

Veterinarians and healthcare professionals are encouraged to inform TMDA of any problems they suspect or encounter related to medical products such as health hazards, adverse drug reactions, adverse events/incidents, malfunctions, non-compliance and any general health concerns that may be linked to regulated products.

The primary responsibility for safety of end users lies on one hand with the medicine or medical device manufacturers and the dispensing pharmacist or veterinary surgeon. Physicians, Pharmacist and other healthcare professionals are responsible for the medical products that they administer, sell or prescribe to end users.

Veterinarians and healthcare professionals should ensure that the medical products they buy, use, or sell are authorized for sale in Tanzania and purchased through a health facility or premises licensed, registered or authorized by TMDA.

Veterinarians and healthcare professionals have professional standards and obligations and it is the responsibility of professional regulatory bodies (such as Medical Council of Tanganyika, Tanzania Nursing and Midwifery Council, Pharmacy Council of Tanzania, Veterinary Council of Tanzania etc.) to ensure that these professional standards are met. Pharmaceutical manufacturers as well as Pharmacists and Veterinarians handling medicines and medical devices must comply with requirements of the Act and its regulations.

6. COMPLIANCE AND ENFORCEMENT ACTIVITIES

TMDA manages the risk posed to public health and safety by medical products through various types of compliance and enforcement activities. TMDA chooses the regulatory actions, tools and level of intervention that are most appropriate for the circumstances, based on a number of factors. Some activities are designed to help regulated parties understand their responsibilities under the Act while others are aimed at inducing or compelling compliance to the law.

6.1 COMPLIANCE ACTIVITIES

TMDA realizes its goals of protecting and promoting public health by investing on efforts to ensure that its stakeholders are aware of and take steps to comply with relevant laws, policies and regulations. The following compliance activities are carried out to assist regulated parties to understand their responsibilities and obligations under the Act and associated regulations.

i. Compliance promotion; and
ii. Compliance monitoring, verification and investigation.

6.1.1 Compliance promotion

Compliance is facilitated when legal and regulatory requirements are clearly identified and understood, and accessible to all stakeholders. TMDA strives to support regulated parties in actively preventing problems from occurring in the first place. TMDA encourages industries and other stakeholders to participate in the development of all quality and safety standards so as to help them become aware of access, understand and comply with the Act and its regulations. Actions under this category aim to minimize risks and may include:

i. Developing and providing education, guidance and information to regulated parties and other stakeholders;

ii. Collaborating and consulting with regulated parties and other stakeholders on quality and safety requirements of the products; and

iii. Development of policies, guidelines and regulations to support compliance.

TMDA compliance promotion focuses on raising awareness and educating regulated parties about their obligations under the Act. TMDA publishes policies and guidance documents so that regulated parties understand TMDA's interpretation of the legislation, the processes to be followed and the scientific standards or principles that will be applied.

TMDA raises awareness amongst regulated parties regarding the range of compliance and enforcement actions available in cases of non-compliance. Compliance promotion also includes providing information to consumers through educational activities and the information sharing on regulatory matters. The Authority also provides information to end users to enable them to be active participants in maintaining their health and the safe use of marketed products.

6.1.2 Compliance Monitoring, Verification and Investigation

TMDA conducts monitoring activities to assess and proactively verify compliance of regulated parties with the Act and its regulations. These proactive activities include a wide variety of fact gathering and assessment activities such as inspections, market surveys, product sampling program and laboratory analysis. Inspections may involve, but are not limited to, actions such as:

i. Physical inspection of a facility, inventories, equipment, product packaging and labeling, electronic documents and promotion advertisement;

ii. Collection and review of documents and records; and

iii. Sample taking for laboratory analysis.

The potential non-compliance may be identified by consumer complaints, industry complaints, distributor complaints, referrals from regional authorities and other regulatory agencies, international partners or the Authority's compliance monitoring activities.

Where the Authority identifies or is notified of a potential non-compliance, steps are taken to determine whether non-compliance has occurred and the health risks that may be posed by products or activities. The frequency, intensity and nature of compliance monitoring activities may vary depending on the health risks identified. TMDA uses the information gathered through compliance monitoring to determine if further regulatory action is required.

TMDA compliance monitoring activities are primarily focused on verifying that products and regulated parties comply with the Act and its regulations and identify risks posed by products or activities. These activities encourage compliance of regulated parties and minimize risks. They may include;

i. Carrying out inspections to verify compliance in response to information regarding known or suspected non-compliance with the applicable requirements of the Act;

ii. Recording, gathering, obtaining or analyzing information on:
    a. products
    b. regulated parties
    c. activities and processes

iii. Taking samples and analyzing products to evaluate compliance and identify risks;

iv. Following up on complaints, incident reports and adverse reactions sent to TMDA; and

v. In appropriate circumstances, sharing information and reports with other regulatory agencies, national or international partners.

6.2 ENFORCEMENT ACTIVITIES

Enforcement actions include any regulatory actions the Authority takes to compel or induce compliance in order to mitigate the risk identified by non-compliance with the Act. Hence TMDA takes enforcement actions to:

i. Bring a regulated party, product, activity or process into compliance with the Act;

ii. Prevent future non-compliance; and

iii. To address detected public health risks.

Where non-compliance is brought to the attention of a regulated party, it is the regulated party's responsibility to take timely and appropriate action to comply with legal and regulatory requirements. Compliance is normally achieved through a cooperative approach among the regulated party and the Authority. However, a number of enforcement options are available if necessary, particularly when the regulated party is unable or unwilling to correct non-compliance. The Authority's role is to ensure that the regulated party complies with regulatory decisions so that ultimate end user of any regulated product has access to safe and quality products.

The primary objective of the response strategy is to manage the risk to the public and use the most appropriate level of intervention to ensure that the responsible regulated party brings the product or activity into compliance. To this end, the Authority evaluates instances of non-compliance to determine the most appropriate action(s) to be taken. Such actions may be undertaken independently,

concurrently or sequentially with other actions, if the circumstances warrant it. This determination considers the various circumstances of each case and takes into account, along with other applicable information using risk-based approaches as described under section 4.3 of this policy.

6.2.1 Regulatory Measures taken by TMDA

TMDA uses a number of regulatory measures to achieve compliance by regulated parties. These are generally exercised under the powers of the Act and its regulations and other relevant legislations, including the *Penal Code Cap 16*.

Depending on requirements of the Act, regulations and level of risk, TMDA may consider the following enforcement actions;

6.2.1.1 Entering into compliance agreements with regulated party

Under certain circumstances, for the purpose of ensuring safety and quality of regulated products, TMDA may establish a written agreement with a person or entity engaged in regulated activities wherein the regulated party agrees to fulfill the requirements of the compliance agreement and comply with the provisions of this policy. Compliance agreement may if necessary have agreed time frame.

6.2.1.2 Preventing the sale, import, advertisement or manufacture of non-compliant products

TMDA is vested with powers to prevent the sale, import, advertise or manufacture of non-compliant products. This may be achieved through inspections, control of imports and exports as well as control and monitoring of promotions and advertisements. All these may lead to recall, seize or relevant legal actions for non-compliant products.

6.2.1.3 Undertaking activities related to seizure, detention and forfeiture of products

An administrative seizure and detention is an enforcement tool for immediately controlling non-compliance. TMDA may take control of non-compliant products under the administrative seizure, detention or forfeiture. When determining whether to implement an administrative seizure, detention or forfeiture, the Authority will consider the risk to health, safety and the compliance history of the regulated party.

6.2.1.4 Imposing financial penalties

TMDA imposes financial penalties in order to compel regulated party to comply with set out standards. The penalties set are in accordance to an offence

committed. The said penalties may be initiated by the Authority or imposed through a court order.

6.2.1.5 Applying for injunctions

The Authority may seek for an injunction order to remedy any risk arising from any product which contravenes the provision of the Act.

An injunction is a court order that intends to maintain a status quo of an existing circumstance. Injunctive action will be considered when a violation constitutes a significant and immediate threat or when a regulated party is non-compliant with a court order.

6.2.1.6 Conducting investigations

In collaboration with other Government organs, TMDA will assess all reported or detected contraventions of the law, regulations and other requirements and prioritize them for compliance and enforcement action. The initial assessment of the investigation typically will include a preliminary examination and analysis of the report or allegation in order to decide its seriousness, the likelihood that a contravention has occurred and the probable consequences. Whenever possible, the Authority will act to prevent a potential infringement.

Based on the initial assessment and the requirements of the law, TMDA will determine the appropriate level of further investigation. The nature, time taken and method of investigation will be determined by the circumstances of the particular incident or contravention. Any investigation is conducted with the following purpose: -

i. Determine whether laws, regulations or other requirement has been contravened;

ii. Determine what, if any, impact has occurred and provide advice or direction on stopping and preventing further impact and any future required actions;

iii. Collect evidence that can be used in prosecutions or that might assist with other appropriate compliance and enforcement measures;

iv. Improve controls to prevent current and future non-compliance;

v. Determine further or similar action which led to the non-compliance;

vi. Improve public confidence in the integrity of the regulatory system;

vii. Achieve an appropriate outcome within a reasonable time; and

viii. Investigate all complicit parties involved in any incident or non-compliance.

6.2.1.7 Recommending prosecution

TMDA may refer the outcome of investigation to the Director of Public Prosecution (DPP) for a legal proceeding in a criminal court and under his jurisdiction determine whether there has been a contravention of the applicable statute or regulation and if so, the appropriate penalty. The Authority considers recommending that charges be laid if the non-compliance of a product or activity can be linked to any of the following criteria:

i. it creates a health risk;
ii. is habitual offender;
iii. was premeditated, indifferent, reckless or a marked departure from a reasonable standard of care; or
iv. other enforcement activities have proven unsuccessful; or suggest that the contraventions will likely appear to continue.

6.2.1.8 Where appropriate, disclosing information through items such as inspection reports

The Authority is determined to uphold privacy of information obtained from regulated parties. However, there may be a circumstantial need to disclose information obtained from regulated party to other related legislative organs in order to foster compliance.

6.2.1.9 Publishing alerts, advisories or other risk communications

It has been a practice for the Authority to provide information on the risks when that information has generated a specific concern or prompted a regulatory action. The Authority utilizes various methods for communicating safety information which include issuance of alerts, advises and letters.

These are tailored to the needs of the primary target audience for each type of information. The public health advisory consists of information and advice regarding an emerging drug safety issue or other important public health information. Other risk communications are delivered using package inserts and summary of product characteristics.

6.2.1.10 Pursuing recalls or other measures to enforce products compliance

The Authority may institute recalls of non-conforming medical products by a regulated party. When a product is recalled, or an advisory or alert is issued, it means the surveillance tools are working. Recalls and safety alerts are sent out

when there is evidence and enough information to believe that non conformances have occurred and there is important information to share.

6.2.1.11 Issuing warning letters

The Authority may issue a warning letter to a regulated party when it is believed that non-compliance has occurred or is continuing and the risk to human health or safety does not warrant an immediate and stronger enforcement action. The Authority will consider the compliance history of the regulated party and any efforts to achieve compliance. Where a warning is ignored or disregarded, or is a third warning letter the Authority may escalate its enforcement activities.

6.2.1.12 Cancelling or suspending market authorizations

When a regulated product is not in compliance with regulatory requirements while significant health risk exists and there is no indication that the regulated party will comply, TMDA may suspend or cancel the marketing authorization of the concerned products.

6.2.1.13 Refusal entry of regulated products at Port of Entry (PoEs)

The Authority may order that a specific product be refused entry and serve such copy of an order to Customs that a product be refused entry into Tanzania on the basis of non-compliance with legal or regulatory requirements. The Authority may order the return to the country of origin of such product or use such other appropriate alternatives to ensure that compliance is done without risk involved.

6.2.1.14 Refusal, Suspension or Amendment of Establishment License

TMDA may refuse, suspend or amend a license of the premises issued by the authority under certain circumstances. Such circumstances are where there are reasonable grounds to believe:

i. that any provisions of the Act and its regulations have been contravened; and

ii. that, the licensee has made a false or misleading statement in its application for a premises license, or the failure to suspend a premises license would constitute a risk to the health or safety of end users.

The Authority may include or amend terms and conditions of premises license, if it is believed on reasonable grounds that it is necessary to do so to ensure compliance.

6.2.1.15 Disposal

The Authority may initiate or order disposal of medical products if it is confirmed that the products are unfit for use. Disposal of unfit products will be done by methods proposed by National Environmental Management Council (NEMC) and supervised by TMDA and other relevant legislative organs. For the purposes of this policy, the disposal will be initiated/performed when;

i. Regulated party has submitted applications for disposal to TMDA.

ii. The inspector condemns and order disposal in circumstances where application for disposal cannot be done such as in remote areas.

6.2.2 Compliance Measures Initiated by the Regulated Party

A number of compliance measures may be considered when it is felt that the risks associated with the non-compliance may be appropriately managed without recourse to regulatory measures. One or a combination of the following measures may be considered.

6.2.2.1 Consent to Forfeit

Consent to forfeit is an agreement between TMDA and the regulated party for the regulated party to surrender control of a product to the government. This shall be done as stipulated under section 99 of the Act.

When the inspector is satisfied that such product is unfit for intended use, he may affix any mark or other designation and where necessary dispose off at the owners cost or destroy in a manner, he may deem appropriate.

6.2.2.2 Recall

A recall is a method for removing a distributed regulated product, including its labeling, that violates the Act and/or its regulations, or that may present a risk to the health of the end user. Recalls of regulated products may be undertaken at anytime, in response to a formal request by the Authority or on the initiative of regulated party to carry out the combined responsibility to ensure compliance with the legislation, and to protect the health of end users. A firm's recall does not preclude other actions which could be taken by the Authority or the firm.

With respect to a regulated product, every person running a business of a product regulated by the Act must maintain such a recall mechanism to enable the removal of distributed non-compliant products.

In implementing recalls, regulated parties are responsible for submission of weekly progress report and later final report in timely manner reflecting quantity recalled

against quantity distributed for reconciliation and further regulatory action. The regulated parties are obliged to conduct a route cause analysis of a non-compliance and submit to the Authority corrective and preventive actions for verification. The recall procedures will be performed as per the recall guidelines.

6.2.2.3 Voluntary Detention

A voluntary detention is an agreement between a regulated party and TMDA to maintain control of a particular product. While the TMDA Act, Cap 219 under section 99 provides authority for product seizure or detention, a voluntary detention under the custody of the regulated party may be appropriate if the Authority is confident that such person carrying on the business will comply with the conditions of the agreement. TMDA will monitor the effectiveness of a detention and may take other enforcement actions, e.g. seizure, as appropriate.

6.2.2.4 Voluntary Disposal

A voluntary disposal is an action by a regulated party to get rid of a product for certain reasons, by actions such as donation, destruction, or returning it to the manufacturer. In considering whether voluntary disposal is an appropriate compliance action, the Authority will consider the following factors:

i. The degree of cooperation offered by a regulated party on prior occasions; and

ii. That the product will be rendered non-saleable/usable.

6.2.2.5 Voluntary Stop Sale

A voluntary consent by the distributor to stop the sale and distribution of a product at any level in the distribution chain for certain reasons.

7.0 INSPECTIONS

Inspection is one amongst the enforcement activities undertaken by TMDA to ensure;

i. Regulated products either locally manufactured or imported meet the set standards of safety, quality, efficacy and performance in order to protect public health; and

ii. Adherence to the laws and regulations governing regulated products and their related activities.

TMDA monitors compliance and detects non-compliance using proactive and responsive inspections undertaken both regularly and comprehensively to prevent incidents. There are five types of inspections;

i. Routine inspection;
ii. Concise inspection;
iii. Follow-up inspection;
iv. Special or investigative inspection; and
v. Audit inspection.

Inspections of regulated products will be carried out by TMDA inspectors in the appropriate manner as provided for in the Act. The Inspectors will take immediate action to control and manage any risks which may arise from contravention of the Act pending any further action as may be found just by the Authority. However, inspections may also be conducted in cooperation with other law enforcement organs.

In exercising their powers for ensuring compliance with the Act and for proper administration of inspections; inspectors will take immediate actions on the following scenarios which contravene the Act or regulations made therein **Table 1**:

Table 1: Examples of violations and their enforcement measures

S/N	OFFENCE	SECTION	PENALTY	COMPUTED PENALTY
1.	Manufacture for sale, sell, supply or store products regulated under the Act in premises that are not registered.	Section 18(4)	Fine of not exceeding 5,000,000 or to imprisonment for a term not exceeding two years or both such fine and imprisonment.	Offence of unregistered Premises cannot be compounded. However, because most businesses are willing to comply, the following measures should be taken; • Order to close premises until permit has been obtained. • For un-renewed business permit give 14 days for permit renewal and penalty after 3 months.

				• Unregistered importers will most likely have other offences like lack of import permit and having unregistered medicines. Actions will be taken accordingly.
2.	Manufacture, import or wholesale products regulated under this Act that are not registered c/s 22(2)(a) and (b)	Section 22(3)	Fine not exceeding 5,000,000 or imprisonment for a term not exceeding two years or both.	This offence can be compounded for wholesale and importers because it was created for Manufacturers and Importers of unregistered products. However, since most of the offenders are just retailers, Inspectors may use the general fine under S.123(1) which is 1,000,000 shillings or imprisonment for 6 months. If repeated the offence can be charged with 12 months imprisonment. Computation of formular under fees and charges Regulations 2022: **1) When medical products will not**

				be subjected for disposal: • Offender can be charged 2% FOB, + 15% of 2% FOB for paying special permit out of time. **2) In case of Products for disposal,** the cost of 25% shall be imposed plus 2/3 of 1000000. **NB**: The 25% Disposal Cost is not a must to apply until when the products are found unfit for use. Take note that, when the Special permits has been retrospectively charged/ granted together with 15% fine. The Products may be allowed to be sold under the Special permits because is not always true that all unregistered products are condemned for disposal (Read section 57 of the Act)
3.	Restriction for sale of products regulated under this Act c/s	Section 22(4)	Fine not exceeding 500,000 or imprisonment not exceeding tree	Offence can be compounded if committed by retailers dealing with

	22(2)(c) and (d) [Registered, appropriate or against license conditions]		months or both.	unregistered medical products. **3) When medical products will not be subjected for disposal:** • Offender can be charged 2% FOB, + 15% of 2% FOB for paying special permit out of time. **4) In case of Products for disposal,** the cost of 25% shall be imposed plus 2/3 of 500000. **NB**: The computation above may apply for the offences of dealing with medical products without appropriate permits or against license conditions.
4.	Manufacture, sale and distribution of undesirable drugs, medical drugs or herbal drugs contrary to Section 60(1)	Section 60(2)	Fine not less than one million shillings or imprisonment for a term of not less than six months or both	The offence cannot be compounded **NB**: The prohibited medical product referred must have been published in the government gazette (GN number)
5.	Violating the conditions for conducting clinical trails.	Section 71	Fine of not less than ten million shillings or to imprisonment for a term of not less than five years or both.	The offence cannot be compounded **NB**: The offence does not relate to the

				fees and charges so the matter may be taken to court for legal action.
6.	Importing and exporting of drugs, medical devices, herbal drugs or poisons into Mainland Tanzania without license or permit in accordance to Section 73(1)	Section 73(6)	Fine of not less than one million shillings or to imprisonment for a term of not less than six months or to both fine and imprisonment.	Computation of formular under fees and charges Regulations 2022: • 2% FOB, + 15% of 2% FOB for Pay out of time without condemning the medical products; and • Incase of Products for disposal the 25% shall be charged plus the 2/3 of 1000000/=
7.	Sale of adulterated or unfit drugs, medical devices and herbal drugs (including expired drugs, medical devices and herbal drugs) C/S 75(1)-(3) & (6)	Section 75(1)-(3) & (6)	Fine of not less than five hundred shillings for an individual and not less than three million for a body cooperate.	Compounding of offence is permitted. Computation of formular under fees and charges Regulations 2022: Disposal fees of 25% shall be charged plus the 2/3 of 500,000/= for an individual and 2/3 of 3,000,000/= for a body corporate.
8.	Manufacture, import, supply, possess or offer for sale any counterfeit drug, herbal drug or medical device c/s 76(1), (2)	Section 76(1), (2)	Fine of not less than five million shillings or to imprisonment for term of not less than two years or both.	1) If the product has been previously identified and analysis conducted and public notice issued, preference first should be taken to court, in the alternative computation of

				formular under fees and charges Regulations 2022: • 2/3 of 5,000,000/= + 25% disposal cost 2) If the product is only suspected to be counterfeit (not officially identified), institute trial by way of Preliminary Enquiry (PE). Take samples for laboratory analysis as per section 101 of TMDA Act that requires to divide samples into three. Once results are out and confirmed to be counterfeit, institute legal proceedings. In case samples taken did not meet the legal requirements of dividing into three, after laboratory analysis consider compounding of offence.
9.	Dealing in any prohibited drugs without permit issued by the Authority in accordance to Section 82(1)	Section 82(2)	Imprisonment for a term of not less than five years and where the convicted person satisfies the court on special circumstances, liable to a fine of not less than five million shillings or to imprisonment for a term not less than	If disposal is required, 25% shall be paid plus 2/3 of 5,000,000

			one year or to both fine and imprisonment.	
10.	Selling or supplying or have in possession for purposes of selling or supplying any product regulated by the Act in a container or package which is not labelled c/s 92(1)	Section 92(3)	If is an individual, fine of not less than five hundred thousand shillings or to imprisonment for a term of not less than three months or both fine and imprisonment.	If disposal is required, 25% shall be paid plus a fine of 2/3 of the 500,000/=
11.	Advertising drugs, medical devices or herbal drugs in a manner that is false, misleading or deceptive or likely to create erroneous impression c/s 98(1), (2) and (4)	Section 98(4)	If is an individual, fine of not less than one hundred thousand shillings or to imprisonment for a term of not less than two weeks or both fine and imprisonment If is a body corporate or association, fine of not less than one million shillings.	If is an individual, fine of 2/3 of TZS 100,000/= may be imposed or for a body corporate a fine of 2/3 of TZS 1,000,000/=. If disposal is required, 25% shall be paid.
12.	Removes, alters or obliterates the mark, seal or other designation with intent to deceive any person.	Section 101(4)	Fine of not less than one hundred thousand shillings or to imprisonment for a term of not less than two weeks or to both such fine and imprisonment.	If disposal is required, 25% shall be paid plus 2/3 of 100000.
13.	Refuses or fails without reasonable excuse, to give any information which he is lawfully required	Section 106(3)	Fine of not less than five hundred thousand shillings or to imprisonment for a term of not less than three months or to both.	Offense cannot be compounded. **Rationale**: It is not related to Fees and charges.

	to give. -Gives any information which is false in a material particular or which he reasonably believes to be untrue -Refuses or fails without reasonable excuse, to give any information which he is lawfully required to give.			
14.	Discloses any particulars or information or fails to comply with the requirements set under Section 107(1) – (3) *	Section 107(4) & (5)	General Penalty S.123	Offense cannot be compounded. Reason: It is not related to Fees and charges.
15.	Usage of certificate of analysis obtained under Section 108(1) for the purpose of advertisement	Section 108(3)	Fine of not more than one hundred thousand shillings or to imprisonment for a term of not less than two weeks or both.	Offense cannot be compounded. **Rationale**: It is not related to Fees and charges.
16.	Offense relating to warranties or certificate of analysis	Section 113	Fine of not less than three hundred thousand shillings or to imprisonment for a term of not less than one month or both such fine and imprisonment.	Offense cannot be compounded. **Rationale**: It is not related to Fees and charges.

17.	Forfeiture	Section 115(1)	General penalty S.123	Offence cannot be compounded. **Rationale**: It is not related to Fees and charges. It is only by court order or other large remedies under the Act.
18.	Operating a product manufacturing facility without key technical personnel,	General Section of Act and Regulation No.16, GMP Regulations, 2018	Fine under general S.123(1) which is 1,000,000 shillings or imprisonment for 6 months. If repeated the offence can be charged with 12 months imprisonment.	Offence can be compounded. Issues a stop order of production for a period that will be specified in the Memorandum agreed and signed by inspectors and facility representatives after which the service of the key personnel will have been secured.
19.	Lack of quality control laboratory in a Manufacturing facility and any other critical deficiency contrary to provision of the Act	General Section 123 of the Act and Regulation No.11, GMP Regulations,2018	Fine under general S.123(1) which is 1,000,000 shillings or imprisonment for 6 months. If repeated the offence can be charged with 12 months imprisonment.	Offence can be compounded. Issues a stop order of production for a period that will be specified in the Memorandum agreed and signed by inspectors and facility representatives after which the deficiencies shall have been corrected.
20.	Falsification of importation documents	Section No.335 of the penal code	Imprisonment for seven years.	Detain the consignment and institute legal procedures.

21.	Premises operating without a superintendent e.g., pharmacist, veterinarian contrary to Regulation No.5 of premises registration Regulations, 2021	General Section 123 of the Act	Fine under General S.123(1) which is 1,000,000 shillings or imprisonment for 6 months. If repeated the offence can be charged with 12 months imprisonment.	May be compounded. For importers, issue three month notice to seek the services of another superintendent. Failure to do so close the premises. For other premises, liaise with Pharmacy council or Veterinary council of Tanzania.
22.	Registered premises found under improper conditions e.g. Not clean, storage temperature and humidity exceed limits, and leakage of the roof contrary to Regulation No.9 of the GSDP Regulations, 2021.	General Section 123 of TMDA Act, Cap.219	Fine under general S.123(1) which is 1,000,000 shillings or imprisonment for 6 months. If repeated the offence can be charged with 12 months imprisonment.	Order to immediately clean the premises. Also order to put in place AC system, and renovating roof as appropriate within 14 days.
23.	Lack of proper documentation and no record-keeping Contrary to Regulation No.34 of the GSDP Regulations, 2021.	General Section 123 of TMDA Act, Cap.219	Fine under general S.123(1) which is 1,000,000 shillings or imprisonment for 6 months. If repeated the offence can be charged with 12 months imprisonment.	• If no purchase documents, compound the offence. • Lack of other documents (e.g Job descriptions, procedures, quality manual), order to put in place a documentation and record system within 14 days.

24.	Manufacture, Sell or use any controlled drug for medicinal or scientific purpose C/S 78 (1)-(4) example failure to retain prescriptions.	Section 78 (1)-(4)	Fine not less than fifty thousand shillings or to imprisonment for a term not exceeding six months or both.	Order for justification. If not satisfactory issue warning letter or based on extent of violation institute legal proceedings.
25.	Sell, Supply, import any product by way of wholesale dealing or retail without permit granted by the Authority for that purpose (eg. *Found in possession of products belonging to Government*)	Section 22(2) (c)	• Fine of not less than five million shillings or to imprisonment for a term not exceeding two years or to both for manufacturers, importers and wholesalers. • Fine not exceeding five hundred shillings or to imprisonment for a term not exceeding three months or to both for retails.	No compounding of offence, Seize the products and institute legal proceedings.
26.	Willfully delaying or obstructing an inspector C/S 106 (3) (a)	Section 106 (3)(a)	• Fine not less than five hundred thousand shillings or imprisonment for a term not less than three months or both.	No compounding of offence. Institute legal proceedings.

Notwithstanding measures instituted by the authority or inspectors the authority shall be at liberty to institute any criminal proceedings before a competent court of Law.

For offenses that are under other institutions such as Pharmacy Council and Veterinary Council of Tanzania, facilities shall be reported to the respective institutions. Examples of such offenses include Retail Pharmacies, Veterinary

Clinics and ADDOs with expired licenses or not registered and falsified Professional credentials e.g., ADDOs certificate etc.

8.0 OBJECTIONS AND APPEALS

TMDA recognizes that some of its decisions may be disputed by regulated parties. In the interest of transparency and fairness, the Authority has implemented internal appeal processes to facilitate the resolution of contentious issues that arise in making some of its decisions (e.g., establishment licensing). The Authority will, however, ensure that such internal appeals do not compromise its compliance and enforcement activities.

8.1 Procedure for objection and Appeals

Any person who is dissatisfied by any action taken under the policy may submit an objection to the Director General or appeal to the Minister on the following procedures: -

a) Notify the Director General of the desire to make objection by written presentations to appear before and be heard by, a person appointed by the Director General for that purpose.
b) A notification of an objection shall be made within fourteen days from the date of action upon which the dissatisfaction relates.
c) The Authority may upon application and on sufficient grounds, extend time for a period of not more than seven days from the date of expiry of the 14 days to present a written objection
d) Where the Authority receives a notification for objection, shall appoint a person to consider the objection.
e) The person appointed shall determine the procedure to be followed with respect to the consideration of any written or oral objections made by the applicant and shall make a recommendation to the Authority.
f) A recommendation made shall be in writing to the Authority, and a copy of it shall be served to the Applicant or his nominated representative.
g) The Authority shall take into account any recommendation made.
h) Within fourteen days of receipt of any recommendation made, the Director General shall inform the Applicant whether he accepts the recommendation and, if he does not accept it, of the reasons for his decision.
i) Where the Director General is notified of an objection, the objection notice shall not take effect until it has been considered and recommended; and
j) the Director General has informed the Applicant concerned of his decision with regard to the recommendations made.
k) Where the Director General is notified of an objection within the period specified to a suspension, revocation or other notice which has already

taken effect on the date the notification was made, such suspension, revocation or notice in respect of which the objection is made shall cease to have effect until the person appointed has considered objection and made a recommendation.

l) The Director General has informed the Applicant of his decision with regard to the recommendation.

m) The objections shall not apply in relation to a suspension or revocation, or a notice served, which takes immediate effect; or

n) in any other case, where the Director General determines that it is necessary in the public interest for the suspension, revocation or notice to take effect on the date originally specified, and serves a notice in writing to that effect on the owner of the premises concerned.

o) A person aggrieved by a decision of any objection made to the Authority may, within sixty days, appeal in writing to the Minister by:

    i) Submitting written grounds of appeal to the Minister and furnish a copy of it to the Authority who shall within fourteen days submit a written response to the Minister and copy the appellant.

    ii) The Authority, may be summoned to appear as the Respondent

    iii) Where the Minister is of the opinion that a case has been made, he may constitute an Adhoc Committee to hear the Appeal, summon parties for additional information or make a decision to allow or dismiss the appeal.

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